F. HIV/AIDS/STDs/RTI

HIV/AIDS

Diagbouga S, Durand G, Sanou PT, Dahourou H and Ledru E. Evaluation of a quantitative determination of CD4 and CD8 molecules as an alternative to CD4+ and CD8+ lymphocyte counts in Africans. Tropical Medicine and International Health 1999;4(2):79-84

Frerichs RR, Htoon MT, Eskes N, *et al*. Comparison of saliva and serum for HIV surveillance in developing countries. Lancet 1992;340(26):1496-1499

Fylkesnes K, Ndhlovu Z, Kasumba K, *et al*. Studying dynamics of the HIV-epidemic: population based data compared with sentinel surveillance in Zambia. AIDS 1998;12(10):1227-1234

Gallo D, George JR, Fitchen JH, *et al*. Evaluation of a system using oral mucosal transudate for HIV-1 antibody screening and confirmatory testing. Journal of the American Medical Association 1997;277(3):254-258

Giles R, Perry K, Parry J. Simple/Rapid Test Devices for Anti-HIV Screening: Do they come up to the mark? Journal of Medical Virology 1999;59:104-9

Goetsch R, Minor J and Piscitelli S. AIDS facts: Home collection and non-blood-based methods of testing for the human immnodeficiency virus. American Journal of Health-System Pharmacy 1997;54(19):2232-5

Kane B. Rapid testing for HIV: Why so fast? Annals of Internal Medicine 1999;131(6):481-3

Kelly PM, Cumming RG, Kaldor JM, *et al*. A new, clinical based algorithm for the diagnosis of HIV in African tuberculosis patients: cross-sectional analysis from Mzuzu, Malawi. International Journal of STDs and AIDS 1999;10:231-236

Lamey PJ, Nolan A, Follett EAC, Coote I, MacFarlane T, Kennedy DH *et al*. Anti-HIVantibody in saliva: an assessment of the role of the components of saliva, testing methodologies and collection systems. Journal of Oral Pathology & Medicine 1996;25(3):104-7

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Nkengasong JN, Bile C, Kalou M, *et al*. Quantification of RNA in HIV type-1 subtypes D and G by NucliSens and Amplicor assays in Abidjan, Ivory Coast. AIDS Research and Human Retrovirus 1999;15(6):495-498

Pasquier C, Bello PY, Gourney P, Puel J, Izopet J. A new generation of serum anti-HIV antibody immunocapture assay for saliva testing. Clinical and Diagnostic Virology 1997;8:195-7

Ray CS, Mason PR, Smith H, *et al*. An evaluation of dipstick-dot immunoassay in the detection of antibodies to HIV-1 and 2 in Zimbabwe. Tropical Medicine and International Health 1997;2(1):83-8

Sato PA, Maskill WJ, Tamashiro H and Heymann DL. Strategies for laboratory HIV testing: an examination of alternative approaches not requiring Western blot. Bulletin of the World Health Organization 1994;72(1):129-134

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Author:	**Diagbouga S, Durand G, Sanou PT, Dahourou H and Ledru E**
Title:	**Evaluation of a quantitative determination of CD4 and CD8 molecules as an alternative to CD4+ and CD8+ lymphocyte counts in Africans**
Source:	**Tropical Medicine and International Health 1999;4(2):79-84**

HIV infection is monitored by determining CD4+ lymphocyte counts. The reference procedure, flow cytometry, is expensive, requires sophisticated instrumentation and technicians with specific training. The Capcellia assay is an enzyme-linked immunoassay for quantitative determination of CD4+ and CD8+ molecules. The article evaluates this method by comparing the Capcellia test with the flow cytometry and haematology procedure. Serum samples were taken from 39 HIV-uninfected and 44 HIV-infected adult subjects from Bobo-Dioulasso, West Africa.

Flow cytometry was performed within two hours on collected samples of whole blood incubated with Cytostat Coulter Clone monoclonal antibodies. The panel run for each specimen assessed the "purity of lymphocyte gates" and the percentage of CD4+ and CD8+ T lymphocytes. The absolute count for each lymphocyte subset was determined by multiplying the WBC count by the percentage of total lymphocytes and by the percentage of the corresponding subset.

"The Capcellia kit is a two-site enzyme immunoassay to determine the concentration of CD4 and CD8 surface molecules on PBMC [peripheral blood mononuclear cells] after immobilization of T lymphocytes by selective immunocapture." Details are given on page 80 of the review.

Carriere at al. (1994) suggested an equivalence between pmol and number of cells: 1pmol/l = 50 x 10^6/l CD4 cells and 1pmol/l = 25 x 10^6/l CD8 cells. The sensitivity of the Capcellia assay is 0.9pmol/l, which corresponds to 0.045 x 10^6/l CD4 T lymphocytes. The accuracy of the Capcellia assay was evaluated in identifying individuals with 0.20 x 10^6/l CD4 + T lymphocytes, because this threshold has been used as the definition of AIDS in some countries. Of the patients with less than 0.20 x 10^6/l CD4 T lymphoctyes, 95% were detected by Capcellia assay using the threshold of 4pmol/l.

The Capcellia assay showed a significant correlation with flow cytometry for low CD4 counts (<400 x 10^6/l), however counts higher than this threshold showed poor agreement according to Bland & Altman (1986). Training and expertise for Capicellia CD4/CD8 are similar as for the ELISA. The reagents for Capcellia are substantially cheaper than flourescence-labelled monoclonal antibodies and other reactives for sample processing used in flow cytomerty. Maintenance of the flow cytometer incurs high costs. The investigators recommend the Capcellia assay where flow cytometric instrumentation is not available and as a complementary method for CD4 T lymphocyte enumeration.

Author:	**Frerichs RR, Htoon MT, Eskes N, *et al.***
Title:	**Comparison of saliva and serum for HIV surveillance in developing countries.**
Source:	**Lancet 1992;340(26):1496-1499**

The purpose of this study was to evaluate the use of saliva as an alternative specimen to serum to identify the frequency of HIV infection in a surveillance program of high-risk and low-risk sentinel groups in Myanmar. Duplicate vials of saliva and serum were collected from high-risk and low-risk subjects. One vial of each pair was analyzed blind in two laboratories one in the USA and the other in Myanmar. The US laboratory followed WHO confirmatory strategy III with

three different enzyme-linked immunosorbent (ELISA) assays which was considered the gold standard, while the laboratory in Myanmar followed strategy I with one ELISA. The Cambridge ELISA with Saliva was a more effective surveillance tool (sensitivity and specificity of 90% and 99.5%, respectively). Saliva is recommended as a safe and effective alternative to serum for HIV antibody testing with ELISA surveillance programs in developing countries.

Author:	**Fylkesnes K, Ndhlovu Z, Kasumba K, *et al*.**
Title:	**Studying dynamics of the HIV-epidemic: population based data compared with sentinel surveillance in Zambia**
Source:	**AIDS 1998;12(10):1227-1234**

The objective of this study was to establish population based HIV survey data in selected populations, and to assess the validity of extrapolation from HIV sentinel surveillance amongst antenatal clinic attendees (ANC) to the general population. The survey was carried out in catchment populations of clinics used for national HIV surveillance. Whereas the sentinel surveillance used serum-based HIV testing, the population survey used saliva. Surveillance of ANC tended to underestimate the overall HIV prevalence of the general population, but the differences were not statistically significant. ANC-based data might draw a rather distorted picture of current dynamics of the HIV epidemic. Even though representing an obvious oversimplification, extrapolations of overall prevalence rates may correlate with that of the general population.

Author:	**Gallo D, George JR, Fitchen JH, *et al*.**
Title:	**Evaluation of a system using oral mucosal transudate for HIV-1 antibody screening and confirmatory testing**
Source:	**Journal of the American Medical Association 1997;277(3):254-258**

The objective of this study was to determine accuracy of a human immunodeficiency virus type-1 (HIV-1) antibody testing system using a device to collect and stabilize oral mucosal transudate (OMT), a fluid with increased levels of IgG; an enzyme immunoassay (EIA) screening test optimized for OMT; and a western blot confirmatory test designed for use with OMT. The OMT specimens were tested by EIA and, if indicated, confirmatory western blot according to a standard testing algorithm. The OMT results were compared with true HIV status as determined by serum testing and/or clinical diagnosis. Sensitivity of the OMT EIA and OMT western blot testing in true positive subjects was 99.9% and 98.8%, respectively. The EIA followed by the western blot yielded a negative result in 99.9% of OMT samples from true negatives. It was concluded that HIV-1 antibody of OMT samples is a highly accurate alternative to serum testing.

Author:	**Giles R, Perry K, Parry J**
Title:	**Simple/Rapid Test Devices for Anti-HIV Screening: Do they come up to the mark?**
Source:	**Journal of Medical Virology 1999;59:104-9**

Thirteen Simple/rapid test devices (S/RTDs) were assessed as alternatives to enzyme-immunoassays (EIAs). EIAs are expensive, require sophisticated laboratory equipment and specific training for technicians and require 1.5 to 2.0 hours to perform. Additionally, positive results with an EIA are followed by a complex and expensive supplementary reaction, such as

Western blotting, to confirm HIV infection. S/RTDs are simple to perform, requiring little or no specialist equipment as well as simple to read. They also require only a few minutes before results are given.

The thirteen S/RTDs were performed on 22 “unremarkable anti-HIV positive specimens” from various risk groups, three anti-HIV 2 positive specimens and 26 sera from blood donors which were unreactive in routine anti-HIV screening. Two commercial anti-HIV seroconversion panels were included, as well as two BBI anti-HIV 1 low titre panels with undiluted samples from asymptomatic donors were selected on the basis of weak reactivity with Western blot, probably reflecting collection shortly after seroconversion.

It was found that the majority of S/RTSs are not as sensitive as the best conventional EIAs, however most devices are of adequate sensitivity. The ease of reading varied greatly between devices, and the S/RTDs that scored lowest for “ease of reading” also scored lowest for sensitivity and specificity.

Of all tests, Cambridge Diagnostics’ Capillus HIV-1/HIV-2 gave rise to the fewest problems of subjectivity, yielding the greatest sensitivity, specificity and ease of reading. Cambridge makes a cheap, battery-powered digital reader that interprets the final result.

This study makes reference to others performed on S/RTSs in the past, indicating that a combination of two carefully chosen screening assays used in pairs, where the initial assay has a higher sensitivity, performs at least as well as EIAs. “ . . .On-site testing with a S/RTS as a screening test in a sexually-transmitted disease clinic resulted in many more patients learning their HIV serostatus, with a saving in overall cost and substantial improvements in the effectiveness of counselling and testing [Kasler *et al*. (1997), On-site, rapid HIV testing with same-day results and counseling, AIDS 11: 1045- 1051.].

Findings on 13 S/RTDs* (from best to worst)					
Assay	Specificity[a] (%) (n=75)	Sensitivity(%) (n=78)	Ease of reading[b]	End-point stability	Approximate time to complere testing of ten specimen (min)
Capillus® HIV-1/HIV-2	100	100	10	~1.5hr	33 (digital) 10 (manual)
Abbot Testpack™ HIV-1/HIV-2	100	100	9.3	>24hr	15
Immunocomb® II HIV-1/HIV-2 BiSpot	100	100	9	>24hr	50
Multispot HIV-1/HIV-2	100	100	8.3	>24hr	22
Bionike AQ™ Rapid HIV Test	100	100	7	~12hr	6
Serodia® HIV-1/HIV-2	100	100	7	~2hr	150
Sero strip HIV-1/HIV-2	100	100	6	>24hr	4.5
HIV Chek ™ 1 + 2 System 3 Test Kit	96	100	9.3	~0.5hr	6.5
HIV-1 & 2 Doublecheck™	96	100	6.7	~8hr	21
Recombigen® HIV-1/HIV-2	92	100	8.3	~4hr	15
SUDS HIV1 + 2	92	100	3	~2hr	17
Uni-Gold™	88	96	7.3	~1hr	13
SeroCard HIV	91	91	3.3	2-3 min	14

*Individual tests' performance has been ranked on the basis of the first three columns of results.
[a]Average scores were calculated from scores of three readers who performed all readings: 1 = very difficult; 10= very easy

Author: **Goetsch R, Minor J and Piscitelli S**
Title: **AIDS facts: Home collection and non-blood-based methods of testing for the human immnodeficiency virus**
Source: **American Journal of Health-System Pharmacy 1997;54(19):2232-5**

Developments in therapy for HIV infection offer incentive for identifying HIV positive cases, though large percentages of at risk persons are not tested and a large proportion are tested after the disease had progressed to AIDS-defining illness. This review details three alternative procedures approved by the FDA.

1. OraSure: Device to collect saliva and oral mucosal fluid which is tested by ELISA for anti-bodies to HIV. Collection must be performed by a trained examiner, subjects must be given an information pamphlet that explains the tests limitations and testing with OraSure-collected oral fluid cannot be used to screen blood donors. The device, containing a treated absorbant cotton fiber pad fixed to a nylon stick, is rubbed between the lower gum and cheek until it is moist, for a minimum of two minutes. Antibodies move from the gingival mucosa onto the pad, and the device is placed into the provided vial of preservative solution, stabilizing the antibodies.

High sensitivity and specificity make this test adequate for preliminary diagnosis of HIV positive cases, though positive results should be confirmed by a blood test, whose specificity is higher. Price is approximately $24.15, available at physicians' offices, public health facilities, private clinics, and AIDS counselling centers.

2. Seradyn Sentinal HIV-1 Urine EIA: Either fresh or previously collected urine is shipped to the laboratory for testing by an ELISA to detect antibodies. The sample is tested twice, and if either test is positive, then a confirmatory blood test is required.

   Sensitivity and specificity are lower than blood tests. The price of each test is $4.25. A confirmatory Western blot for urine speciemens is waiting FDA approval.

3. Confide/Home Access HIV-1 Test System: Home collection devices that allow individuals to self-collect samples and receive test results anonymously. Home collection may aid HIV diagnosis because people can avoid public testing sources and venues. Also, such tests may encourage returning for results.

   Confide was withdrawn from the market due to weak sales, but offered a 100% sensitivity and a 99.95% specificity.

   For both tests, individuals puncture a finger and blot blood onto the test card. The card is mailed in a protective envelope to the laboratory, where testing with ELISA occurs. If the initial reaction on the ELISA indicates positive antibodies, a confirmatory Western blot is performed. Home Access demonstrated a 100% correlation with positive and negative results obtained by veni-puncture and standard testing. Home Access costs $25 – 50.

Author:	**Kane B**
Title:	**Rapid testing for HIV: Why so fast?**
Source:	**Annals of Internal Medicine 1999;131(6):481-3**

The update on HIV rapid testing describes issues surrounding acceptance of rapid testing and mentions performance of particular assays. "Outside the US, testing algorithms consisting of two rapid tests used in tandem yield results as good as those confirmed by Western blot." The FDA has approved one rapid test for HIV diagnosis, the screening enzyme immunoassay as a single-use diagnostic system (SUDS). More rapid tests are soon to be FDA approved, including the QUIX test, which correlated with 100% with results obtained by Western blot. The advantage of rapid tests is the ability to immediately notify subjects of HIV status. It was determined that use of rapid testing rather than standard testing would have allowed almost 700000 more persons to learn their true HIV status.

Author	**Kelly PM, Cumming RG, Kaldor JM, *et al.***
Title:	**A new, clinical based algorithm for the diagnosis of HIV in African tuberculosis patients: cross-sectional analysis from Mzuzu, Malawi**
Source:	**International Journal of STDs and AIDS 1999;10:231-236**

The aim of this study was to create an improved, clinically-based algorithm for the diagnosis of HIV in tuberculosis patients. Cross-sectional analysis was performed on data from adult TB

patients consecutively diagnosed at a Malawian district level hospital. Urban address, history of skin rash and sexually transmitted diseases (STDs) and, on examination, oral candidiasis and lymphadenopathy were associated with HIV co-infection. Using these clinical characteristics, a case definition for HIV was constructed. The Mzuzu clinical case definition was highly sensitive (86%). The area under the receiver operating characteristic (ROC) curve was 0.81, significantly larger than existing World Health Organization clinical case definitions. The Mzuzu definition is proposed for further evaluation in settings where HIV serology testing is not readily available.

Author:	**Lamey PJ, Nolan A, Follett EAC, Coote I, MacFarlane T, Kennedy DH *et al*.**
Title:	**Anti-HIVantibody in saliva: an assessment of the role of the components of saliva, testing methodologies and collection systems**
Source:	**Journal of Oral Pathology & Medicine 1996;25(3):104-7**

Testing on various components of saliva yield differing values for sensitivity and specificity. A commerical test system, Wellcozyme HIV 1 and 2 and an anti-body capture ELISA (GACELISA) were compared for sensitivity against all components. Mixed saliva was most conveniently collected with Salivette samples, and the most sensitive method was collection of mixed saliva with monitoring by GACELISA assay.

	Percent Sensitivity (n = sample size)	
Saliva Type	**Wellcozyme**	**GACELISA**
Mixed (n = 123)	92	100
Parotid (n = 121)	55	100
Labial (n = 127)	73	100
Submandibular (n = 99)	66	98
Crevicular (n = 127)	63	99
Salivette collection (n = 241)	95	100
Dry swab collection from gingival margin (n = 197)	81	98

Author:	**Lillo F, Varnier OE, Mantia E, Terragna A, van der Groen G, Van kerckhoven I *et al*.**
Title:	**Detection of HIV-1 antibodies in blood specimens spotted on filter-paper**
Source:	**Bulletin of the World Health Organization 1992;70(3):323-6**

Epidemiological monitoring can be hampered by the difficulty in obtaining blood, and storage of aliquots may be difficult in developing countries. The use of blood spotted on filter-paper (BSP) has been used to evaluate metabolic disorders in newborns. BSP has unique advantages over use of serum samples that make this technique suitable for use in developing countries. Equipment requirements are minimal and filter cards are light and durable, allowing the samples to be stored at room temperature for several weeks and sent by mail.

The present international collaborative study assessed the usefulness of six different HIV antibody assays of BSP samples, using paired BSP and serum samples from forty patients attending the Clinic of Infectious Diseases, Genoa. Whole blood is spotted slowly on a paper disc,

diameter of 5mm, until blood saturates the paper. Cards were placed in sealed plastic bags, kept room temperature until the blood had dried and sent to the laboratory.

The Behring Enzygnost Anti-HIV Micro ELISA, the GACELISA and the GACPAT obtained optimal results, each detecting antibodies in all the positive BSP ans serum samples, without any false reactions and with a final 100% concordance, demonstrating that some kits can be easily adapted to test BSP samples.

Other kits were less successful. The DuPont HIV recombinant (ENV9) ELISA showed concordance between BSP and serum results with one exception of one negative sample that was initially reactive with the BSP. The Cellular Product Inc. ELISA detected the presence of HIV-1 antibodies in all positive BSP and serum samples, however five HIV-1 seronegative BSP samples were initially reactive and two of these were repeatedly reactive on retesting. The Serodia-HIV particle-agglutination test showed the least concordance.
Magnusson RS. Testing for HIV without specific consent: a short review. Australian and New Zealand Journal of Public Health 1996;20(1): 57-60

The practice of testing for human immunodeficiency virus (HIV) without the specific knowledge and consent of the patient raises ethical and legal issues. This report argues that diagnostic HIV testing of specific patients without their consent is unethical and may also be illegal. Testing for HIV prevalence on an anonymous, unlinked basis, however, is an important aspect of public health surveillance, and the ethics of clinical intervention should not be confused with ethics of epidemiological research. Specific consent is usually desirable in view of privacy concerns, the importance of patient autonomy, and the potential for conflict of interest. However, where otherwise appropriate, the law should be clarified to permit nonconsensual HIV testing to proceed legally, possibly following scrutiny by an institutional ethics committee.

Author:	**Matee MIN, Lyamuya EF, Simon E, Mbena EC, Kagoma C, Samaranayake LP *et al.***
Title:	**Detection of anti-HIV-1 IgG antibodies in whole saliva by GACELISA and Western blot assays**
Source:	**East African Medical Journal 1996;73(5):292-4**

The present study based on 158 seropositives and 167 seronegatives, demonstrates that saliva collected with the Omni-SAL^{TM} device and tested with GACELISA (an IgG antibody capture assay) is an effective, non-invasive alternative to serum for anti-HIV IgG antibody screening.

The study also shows that Western Blot can be used to confirm preliminary results.

Acceptance rate with Omni-SAL^{TM} amongst subjects was high (96%). Of the Tanzanian study participants, 65% preferred to give saliva than to give blood collected by venipuncture. High sensitivity (100%) was obtained with the use of a single GACELISA, so it can be used confidently to dtect anti-HIV IgG. Saliva collection takes less than three minutes, many individuals can be sampled at once. Because saliva collection is simpler, it is probably cheaper than blood collection, though cost was not assessed.

The high sensitivity ensures sufficiency for epidemiological surveillance, and coupled with a high specificity, GACELISA can be used for diagnostic purposes as well. In order for the results to be reported to the subject, however, a second, confirmatory test must be performed. Western Blot

performed on serum of 165 HIV positive subjects for IgG antibodies gave a specificity of 97.4%, indicating this test is sufficient for confirming the GACELISA for diagnostic purposes.

Author:	**Nkengasong JN, Bile C, Kalou M, *et al*.**
Title:	**Quantification of RNA in HIV type-1 subtypes D and G by NucliSens and Amplicor assays in Abidjan, Ivory Coast**
Source:	**AIDS Research and Human Retrovirus 1999;15(6):495-498**

This study assesses the ability of two commercially available HIV-1 viral load assays (NucliSens and Amplicor) to quantify RNA levels in the plasma of patients infected with subtype D and subtype G strains. Serum was taken from 12 tuberculosis patients infected with HIV-1 *env* subtype D and *env* subtype G in Ivory Coast. It was demonstrated that both the modified Amplicor and NucliSens assays can quantify RNA in persons infected with HIV subtypes D and F, with the modified Amplicor demonstrating better performance based on higher sensitivity as well as a higher number of copies of RNA.

Author:	**Pasquier C, Bello PY, Gourney P, Puel J, Izopet J**
Title:	**A new generation of serum anti-HIV antibody immunocapture assay for saliva testing**
Source:	**Clinical and Diagnostic Virology 1997;8:195-7**

To more easily evaluate HIV prevalence, particularly in high risk groups and under difficult field conditions, a new assay for anti-HIV antibody was performed on saliva. Testing on saliva is more readily accepted than serum testing and may permit the screening of populations that have little medical care. The GACELISA HIV 1+2 assay has been widely used, however this generation of assays was unable to detect HIV-1 O-subgroup and IgM subclass antibodies.

The ICE HIV-1.0.2 assay (Murex Diagnostics) has been recently developed for testing sera, and the suitability for use on saliva is assessed here. Sensitivity and specificity have been estimated by comparing ICE HIV-1.0.2 assay for saliva with results of this test on serum from samples given by 530 patients at Purpan University hospital. Sensitivity of the serum and saliva assays were 100% and 99.8%, respectively, and high specificity, with only one discordant case (scored positive in the saliva). The investigators believe that the ICE HIV-1.0.2 is an efficient tool for HIV testing

Author:	**Ray CS, Mason PR, Smith H, *et al*.**
Title:	**An evaluation of dipstick-dot immunoassay in the detection of antibodies to HIV-1 and 2 in Zimbabwe**
Source:	**Tropical Medicine and International Health 1997;2(1):83-8**

This study evaluates a simple, low-cost dipstick-dot immunoassay in the detection of antibodies to HIV-1 and 2 in Harare, Zimbabwe. A panel of 546 sera selected from frozen stocks maintained by the Zimbabwe AIDS prevention Project in Harare were used for the evaluation. Sera were first tested by Abbott recombinant peptide HIV-1 and 2 ELISA and Enzygnost synthetic peptide HIV-1 and 2 ELISA. After thawing sera were again tested using the Abbott recombinant peptide HIV-1 and 2 ELISA and concurrently with the synthetic peptide ICL-Dipstick. Both sensitivity and specificity of the ICL Dipstick exceeded 99% when using sera that were positive or negative in

all 3 plate ELISAs as the gold standard. When using sera that gave discrepant results between the two pre-storage ELISAs most results with the ICL dipstick concurred with findings from other test systems, including western blot and p24 antigen detection. Considering the accuracy, low cost and case of operation of the ICL dipstick ELISA, this test can be recommended for use for the rapid detection of antibodies to HIV at district level in developing countries.

Author:	**Sato PA, Maskill WJ, Tamashiro H and Heymann DL**
Title:	**Strategies for laboratory HIV testing: an examination of alternative approaches not requiring Western blot**
Source:	**Bulletin of the World Health Organization 1994;72(1):129-134**

Western blot testing is expensive and technically demanding, so ELISA/simple/rapid testing (ESR) is explored here. This review examines three strategies that employ a combination of ELISA tests, "simple" tests and/or "rapid" tests. Simple tests are easier to use, requiring no additional laboratory equipment, and rapid tests determine the results in 30 minutes or less. The current study examined three strategies of employing ESR testing to determine a method as sensitive as the Western blot for diagnosing HIV. Testing was performed with a single ERS test (Strategy I), testing all samples with a second ESR that were reactive in intial testing (Strategy II) and further testing all samples that were reactive in each of two sequential ERS tests (Strategy III). The following table details information on specifications used in the study:

	HIV test specifications used in the study		
	Sensitivity (%)[a]	Specificity (%)[a]	Estimated cost per assay (US$)[b]
ELISA	99.0	99.0	1.50[c,d]
Rapid test	99.0	99.0	3.00[e]
Simple test	99.0	99.0	1.00[e]
Western blot	99.0	99.99	25.00[c,f]

[a]Values obtained by an international reference laboratory.
[b]Inclusive of related costs, such as staff and ancillary equipment.
[c]Suitable for laboratories with high HIV-testing volume.
[d]Require the availability of an ELISA reader, and ELISA washer, and AC power supply and laboratory consumables.
[e]Suitable for laboratories with either high or low testing volume.
[f]Requires laboratory equipment.

The positive predictive values (PPV) at a 10% prevalence rate 91.7% with Strategy I, 99.9% with Strategy II and >99.9% with Strategy III. The highest negative predictive values (NPV) was obtained with Strategy I. Based on the PPV and NPV, the following uses were assigned for each strategy:

Proposed HIV testing strategies, by testing objective and HIV prevalence		
Objective of testing	HIV prevalence (%)	Laboratory testing strategy
Identification of asymptomatic	Less than or = 10	III
HIV-infected persons	Greater than 10	II
Diagnosis of HIV-related illness	All	II
Serosurveillance	Less than or = 10	II
	Greater than 10	I
Transfusion safety	All	I

Author: **Schramm W, Angulo GB, Torres PC, *et al*.**
Title: **A simple saliva-based test for detecting antibodies to Human Immunodeficiency virus**
Source: **Clinical and Diagnostic Laboratory Immunology 1999;6(4):577-580**

This study was performed to determine the feasibility of using saliva as a diagnostic medium for the detection of antibodies to human immunodeficiency virus type-1 (HIV-1) and HIV-2 under nonlaboratory conditions and to evaluate the performance characteristics of such a test. For this purpose a self-contained kit (Saliva-Strip ST), which combines the collection and processing, as well as the analysis of the specimen. The kits performance was evaluated in a blinded study. Sera was tested using an enzyme linked assay (EIA) and a rapid strip test. Sera reactive in one of the assays were also analyzed by western blot. Sensitivity and specificity were 99.4% and 99.4%, respectively for saliva test trip and 100 and 99.1%, respectively for EIA and 99.7 and 100%, respectively for the serum test strip. It is concluded that this non-invasively obtained medium may be suitable for use in the field where laboratory support and personnel are limited, such as community outreach programs, doctors' offices, surveillance studies and community hospitals.

Author: **Stetler HC, Granade TC, Nunez CA, *et al*.**
Title: **Field evaluation of rapid HIV serologic tests for screening HIV-1 infection in Honduras**
Source: **AIDS 1997;11(3):369-375**

This report describes the Centers for Disease Control and Prevention/ Honduras Ministry of Health (CDC/HMH) field evaluation of testing strategies carried out during 1992-1993 at multiple sites in Honduras. This study evaluated different HIV serologic tests and test combinations under the field conditions existing in Honduras. Its aim was to identify strategies that would permit the completion of the HIV antibody screening as well as the diagnostic reporting in < 1 hour at all testing sites using simple, rapid immunoassays. Findings show that combinations of rapid, simple HIV antibody assays provide sensitivity and specificity performance that are comparable to EIA/Western blot. Applications of these combinations in the WHO alternative testing strategies provides an inexpensive and effective method of determining HIV status. Assay combinations using these strategies can be easily performed in small, rural laboratories and have been implemented in routine HIV screening in Honduras.

Author:	**Stuart JM, Irlam JH, Wilkinson D.**
Title:	**Routine reporting or sentinel surveys for HIV/AIDS surveillance in resource-poor settings: experience in South Africa, 1991-1997**
Source:	**International Journal of STDs and AIDS 1999;10:328-330**

Information from routine and sentinel surveillance was used to monitor the HIV/AIDS epidemic in Kwa-Zulu Natal between 1991 and 1997. This paper presents findings from the comparison made between data obtained from 1) sentinel surveillance for antenatal HIV infection, pulmonary Tuberculosis (PTB) and AIDS in a single district and 2) province wide sentinel surveillance for antenatal HIV infection, legally required notification of cases of PTB, and voluntary notification of AIDS cases. Routine disease notification and voluntary reporting systems are likely to underestimate the impact of HIV/AIDS epidemic in resource poor settings. Sentinel surveillance at representative sites should be developed to validate or replace passive surveillance systems.

Author:	**Tamashiro H and Constantine NT**
Title:	**Serological diagnosis of HIV infection using oral fluid samples**
Source:	**Bulletin of the World Health Organization 1994;72(1):135-43**

The serological identification of antibodies to human immunodeficiency (HIV) in the blood is the most widely used method to diagnose HIV infection, however the use of oral fluid, including saliva and crevicular fluid, for the detection of antibodies has been suggested as an alternative. This article reviews basic information testing of oral fluid testing for HIV, saliva collection methods, collection devices, collection compliance and accuracy of testing and assay performance with oral fluid samples. Most studies that examined oral fluids for HIV testing have applied methods designed for testing serum or plasma to oral fluids, such as ELISAs and the Western blot, though rapid and simple non-ELISA tests have also been evaluated for testing oral fluids. Most ELISAs, a particle agglutination assay (PAT), several rapid assays, and Western blots can be used to test oral fluids with a sensitivity of 95 – 100%. Specificities were excellent, ranging from 99.5 – 100%, suggesting that these tests are appropriate epidemiological tool or a possible confirmatory strategy. The GAC ELISA, the only test designed specifically for oral fluid testing, was excellent (sensitivity, 98 – 100%; specificity, 97.7 – 100%).

Advantages:

- safer collection because occupational risk from needle-stick, disposal of needles and cuts from broken glass tubes are eliminated
- safer collection because viral infection in saliva is lower than in blood
- safer collection because the disposable risk of oral fluids is minimized
- more simple collection than venous blood
- adequate amounts can be more easily obtained than blood
- cost minimization because of minimal training of personnel
- cost minimization because samples can be collected simultaneously from groups
- higher degree of collection compliance reduces sampling bias

Disadvantages:

- difficulties in conducting unlinked anonymous studies for sentinel surveillance
- potential degradation of the proteins, including immunoglobins, if stabilizers are not added
- possibility that certain fluids may not posses sufficient antibodies

- difficulties in obtaining large volumes of saliva for quality control are much more difficult to obtain than blood
- possibile concern about transmission of certain infectious agents, such a *Mycobacterium tuberculosis*

Oral fluid samples may offer many advantages, and most studies indicate the potential for accurate detection of antibody. However, few studies have been performed by independent investigators have been performed, and there is insufficient evidence to justify the routine use of these fluids at present. The existence of several types of oral samples, the availability of different collection devices and the large number of HIV tests dictate the need for further studies.

Author:	**Toye P, Riyat MS**
Title:	**Specificity of a novel red blood cell agglutination assay ('SimpliRED') for HIV-1/HIV-2 infection**
Source:	**East African Medical Journal 1997;74(4)237-8**

The 'SimpliRED' is serological assay with a monoclonal antibody specific for human erythrocytes which is chemically conjugated to synthetic antigenic peptides from gp41. In the presence of HIV-1 antibodies, the conjugated monoclonal antibody causes cross-linking of the erythrocytes and visible agglutination within two minutes. The assay was used on 125 blood donor samples in Nairobi with a specificity >99%. The assay correctly identified five positive samples and was easy and rapid to perform. The test is suitable for use in developing countries because it is inexpensive, easy to use and interpret, is performed without expensive ancillary equipment, water and/or electric supplies.

Author:	**UNAIDS/WHO**
Title:	**Revised recommendations for the selection and use of HIV antibody tests**
Source:	**Weekly Epidemiological Record 1997;72(12):81-88**

Recommendations for the selection and use of HIV antibody tests were first issued by WHO in 1992. Since then the range of HIV antibody tests available has expanded. New types of assays have been developed and the overall quality has improved. HIV tests for other body fluids (saliva and urine) have been developed. The testing strategies described in these recommendations should only be applied to tests using serum or plasma. Three testing strategies are recommended by WHO/UNAIDS. Choice of a testing strategy, the selection of the most appropriate test or combination of tests to use, depends on three criteria; the objective of the test, the sensitivity and specificity of the tests being used and the prevalence of HIV infection in the population being tested.

Author:	**Urnovitz H, Sturge J, Gottfried T, Murphy W**
Title:	**Urine antibody tests: New insights into the dynamics of HIV-1 infection**
Source:	**Clinical Chemistry 1999;45(9):1602-13**

Non-invasive methodologies fir HIV testing provide alternatives to diagnostic tests and increase safety, reduce costs and encourage participation in HIV testing. The FDA licensed the first screening EIA for the detection of urine antibodies in 1996 and the Western blot for the one-band

gp160 confirmation test for urine antibodies was licensed in 1998. The recominant gp160 envelope protein is adsorbed onto the walls of a micro-well plate. Urine specimen are added to the wells and incubated, and any present antibodies bind to the antigen coated on the well, causing the color to change to yellow. The absorbance values are read spectorphotometrically.

To assess the sensitivity and specificity of the urine-based HIV test, urine and blood specimen were collected from 11896subjects at six sites representative of the US population. HIV-1 urine antibody enzyme immunoassay (EIA) screening tests and subsequent Western blot were performed on the paired urine and blood samples. The serum test detected 99.15% of all antibody-positive individuals compared with the urine test, which detected 98.73% HIV infection of the same cohort. The frequency of urine-negative/serum positive was 0.17%, and the frequency of urine-positive/serum-negative was 0.24%.

In a second study of 25991 subjects, the false-positive urine EIA was 1.3%. False positive frequency was attributed to IgA antibody response. An analysis was carried out to determine factors that influence indeterminate Western blot reactivities. Data indicate that antibodies from seroindeterminate HIV-1vau group O are reactive in urine EIA and Western blot tests. The HIV-1vau strain group O env nucleotide was homologous with human chromosome 7q31, a fragile site implicated in many human malignancies.

Author:	**Walther-Jallow L, Andersson S, Da Silva Z, *et al*.**
Title:	**High concordance between polymerase chain reaction and antibody testing of specimens from individuals dually infected with HIV types 1 and 2 in Guinea-Bissau, West Africa**
Source:	**AIDS Research and Human Retroviruses 1999;15(11):957-962**

This study evaluates the concordance between serology, using five commercially available antibody assays designed to discriminate between HIV-1 and HIV-2, and the polymerase chain reaction (PCR) for the detection of HIV-1 and HIV-2 dual infection. Thirty seven HIV-1 and HIV-2 dually reactive serum samples from individuals in Guinea-Bissau with total $CD4^+$ T Lymphocyte counts ranging from 9 to 948 * 10^6/liter were included in the study. All samples were tested by Multispot, Pepti-LAV and Immunocomb HIC-1 and HIV-2 discriminatory antibody assays. Most samples were also tested by a combination of two HIV type specific antibody enzyme-linked immunosorbent assays (ELISA). Each sample showed dual reactivity in all or any of these assays. A nested PCR based on primer systems were used to evaluate the serological results. The type specificity on the serological assays and PCR was 77.7% for Multispot, 80% for Pepti-LAV, 81.8% for Immunocomb and 85.7% for the two ELISAs used in combination. The majority of individuals included in this study appeared to be truly dually affected. The study shows that it is possible, through a careful selection of assays, to reach a high concordance between serological assays and PCR in studying HIV-1 and HIV-2 dual infections.

Author:	**Wesley E.**
Title:	**Accuracy of oral specimen testing for human immunodeficiency virus**
Source:	**American Journal of Medicine 1997;102(Suppl4A):15-20**

The purpose of this article is to explore the potential of oral fluid as a testing medium and to assess the accuracy of the assays that are used. Antibodies to human immunodeficiency virus (HIV)can be detected in oral fluid with great accuracy, due to technical advances in both the

collection of oral samples and assays. Reported sensitivities of 97.2-100% and specificities of 97.7-100% compare well with those of serum-based assays and qualify oral fluid for the screening and diagnosis of HIV infection in both high and low risk populations. In addition, oral fluid offers several advantages over serum as a testing medium for HIV, including greater safety, ease of collection and patient acceptability.

Author:	**Wilkinson D, Wilkinson N, Lombard C, *et al*.**
Title:	**On-site HIV testing in resource poor settings: is one rapid test enough?**
Source:	**AIDS 1997;11(3):377-381**

The aim of this study was to determine the feasibility, accuracy and cost-effectiveness of rapid on-site testing strategy for HIV infection in a rural hospital, and to assess the impact of this strategy on test turnaround time and the proportion of patients post-test counseled. Two testing strategies (double rapid test on-site versus central enzyme-linked immunoabsorbent assay (ELISA)-based testing) were compared and economically evaluated. It was concluded that in high prevalence and resource poor settings, rapid, on-site HIV-testing is feasible, accurate and highly cost-effective and increases the number of patients post-test counseled. A single rapid test may be sufficient.

Author:	**Windsor IM, Gomes dos Santos ML, De La Hunt LI, Wadee AA, Khumalo S, Radebe F, Dangor Y, Ballard RC**
Title:	**An evaluation of the capillus HIV-1/HIV-2 latex agglutination test using serum and whole blood**
Source:	**International Journal of STD & AIDS 1997;8:192-5**

Increasing cost of HIV testing imposes increasing strain on health budgets of developing countries, so routine use of Western blot testing for HIV has become less common. The adoption of alternate strategies consistent with those recommended by the World Health Organization is necessary, however the optimum test for HIV diagnosis in developing countries must be determined. The Cambridge agglutination test is simple to perform, so its performance is assessed.

A total of 289 HIV-positive sera and 323 HIV-negative sera plus 50 individual seroconversion samples were tested by capillus, and using a digital reader, sensitivity and specificity were both 100%. Visual reading by three independent gave an initial sensitivity value of 98.55% and an initial specificity of 100%.

Paired blood specimens were also collected from 501 consecutive patients with newly diagnosed sexually transmitted diseases. Capillus testing showed 100% sensitivity and 99.7% specificity.

Author:	**Zaw M, Frerichs RR, Oo YK, *et al*.**
Title:	**Local evaluation of a rapid HIV assay for use in developing countries**
Source:	**Tropical Medicine and International Health 1999;4(3):216-221**

The purpose of this study was to evaluate human immunodeficiency virus (HIV) test kits for use in rural hospitals lacking adequate laboratory facilities and the field validity of the Sero-Strip HIV ½ rapid test was assessed. Serum specimen was first tested with the Genelavia HIV Mixt enzyme

immunoassay (EIA) and then confirmed reactive or nonreactive with the Vironostika HIV Mixt EIA and the Detect HIV EIA following UNAIDS Testing III strategy. After one short training session, laboratory technicians at four township hospitals sent 800 sera, labeled with only one identification number. Testing of sera was done with the Sero-Strip HIV ½ rapid test. All true positives were correctly identified as were all but 2 true negatives, resulting in a sensitivity and specificity of 100 and 99.5%, respectively. These findings were similar to those of other researchers in multiple settings.

Sexually Transmitted Diseases (STDs): General

Bayer R. Ethical Issues. In: Sexually Transmitted Diseases. Chapter 107, pp. 1449-54. 3rd Edition. McGraw Hill, New York;1999

Chernesky M, Morse S, Schachter J. Newly available and future laboratory tests for sexually transmitted diseases (STDs) other than HIV. Sexually Transmitted Diseases 1999;26(S4):S8-S11

Mertens TE, Kassler WJ. Evaluation of Sexually Transmitted Diseases and HIV/AIDS Prevention Programs. In: Sexually Transmitted Diseases. Chapter 98, pp. 1353-66. 3rd Edition. McGraw Hill, New York;1999

Morten AN, Wakefield T, Tabrizi SN *et al*. An outreach programme for sexually transmitted infection screening in street sex workers using self-administered samples. International Journal of STDs & HIV 1999;10:741-43

Stanton C. Ethiopian Reproductive Health Survey: STD Pilot Study. Macro International Inc., Calverton, Maryland;1997

Tam RM. Laboratory. Diagnosis of Sexually Transmitted Diseases in Resource-Limited Settings. In Sexually Transmitted Diseases. Chapter 103, pp. 1409-20. 3rd Edition.McGraw Hill, New York;1999

Wasserheit J. The significance and scope of reproductive tract infections among third world Women. International Journal of Gynecology and Obstetrics 1989;30(Suppl 3):145-168

Wawer JM, Gray RH, Sewankambo NK, Serwadda D, Paxton Lynn, *et al*. A randomized, community-based trial of intensive sexually transmitted disease control for AIDS prevention. AIDS 1998;12:1211-1225

Author:	**Bayer R**
Title:	**Ethical Issues**
Source:	**In: Sexually Transmitted Diseases. Chapter 107, pp. 1449-54. 3rd Edition. McGraw Hill, New York; 1999**

This chapter highlights ethical issues that have emerged in the context of the HIV/AIDS epidemic. Topics reviewed include the ethics of prevention (typically stressing mass education), counseling and voluntary testing as well as the protection of confidentiality. In the discussion on confidentiality the author touches on the physician's responsibility when an HIV infected patient refuses to inform identifiable, unsuspecting past or current partners about the dangers of infection. Ethics in global HIV/AIDS research are discussed and examples of previously conducted studies are presented. The last topic of this chapter focuses on the ethics of care including the physician's duty to treat a patient infected with HIV and the need to improve access to care for all populations.

Author:	**Chernesky M, Morse S, Schachter J**
Title:	**Newly available and future laboratory tests for sexually transmitted diseases (STDs) other than HIV**
Source:	**Sexually Transmitted Diseases 1999;26(S4):S8-S11**

The goal of this paper is to review the advantages and disadvantages of current and future diagnostic approaches of STDs. The increase in analytical sensitivity afforded by nucleic acid amplification (NAA) has enabled the use of non-invasive specimen, such as first-void urine (FVU) and self-obtained vaginal swabs, for diagnostic testing and screening asymptomatic low-prevalence populations and hard-to-access populations. This technology allows multiplexing in which targets from multiple agents responsible for a particular syndrome can be amplified and detected. NAA tests are a great improvement and additional tests are needed for the diagnosis of STDs at the point of first encounter, with minimal delay between diagnosis and treatment. Affordable tests, which are rapid, sensitive, and specific are needed for use in resource-limited settings where most STDs are seen. This has been a major undertaking for the Sexually Transmitted Disease Diagnostic Initiative.

Author:	**Mertens TE, Kassler WJ**
Title:	**Evaluation of Sexually Transmitted Diseases and HIV/AIDS Prevention Programs**
Source:	**In Sexually Transmitted Diseases. Chapter 98, pp. 1353-66. 3rd Edition. McGraw Hill, New York; 1999**

A variety of possible approaches for the evaluation of STD and HIV/AIDS programs and projects are described. The objective of evaluation research is to provide information to decision-makers. Guidance is given on how to select an appropriate evaluation design and method. The authors stress that independent of the design or method chosen the evaluation process should be based on a participatory approach. Planners, program officers and program participants should be involved to increase the action taken on the results of the evaluation.

Author:	**Morten AN, Wakefield T, Tabrizi SN *et al*.**
Title:	**An outreach programme for sexually transmitted infection screening in street sex workers using self-administered samples**
Source:	**International Journal of STDs & HIV 1999;10:741-43**

This paper describes a cross-sectional study of street sex workers in Melbourne, Australia using a self-administered method to detect chlamydia, gonorrhea and trichomonas infections. Comparative data was collected from brothel sex workers attending the main sexual health clinic in Melbourne. Women's specimen were collected through self-inserted tampons, which were placed into a transport medium immediately after collection. Men were asked to provide first passed urine. Samples from street workers were brought to a laboratory and analyzed for Neisseria gonorrhea, Trichomonas vaginalis and Chlamydia trachomatis by Polymerase Chain Reaction (PCR). Samples positive for N. gonorrhea were confirmed using Roche Amplicor kit and sequenced using Prism cycle sequence kit. Results demonstrate that this method of testing for STIs was acceptable to street sex workers and showed that this type of outreach program can have a high yield with regard to asymptomatic infection in this group.

Author:	**Stanton C**
Title:	**Ethiopian Reproductive Health Survey: STD Pilot Study**
Source:	**Macro International Inc., Calverton, Maryland; 1997**

The purpose of this report is to document the training, methodology and results of an STD pilot study in the Southern Ethiopian People's Region. This study was conducted as one component of the preliminary research carried out in preparation for the Ethiopian Reproductive Health Survey (ERHS). The study protocol included specimen collection (blood, urine and vaginal swabs) at household level for the detection of anemia and certain STDs. For Gonorrhea and Chlamydia vaginal swabs and urine were collected and analyzed using Ligand Chain Reaction (LCR). Trichomonas and bacterial vaginosis were both detected from vaginal swabs. Syphilis was diagnosed using the TRUST assay, a nontreponemal test. Confirmatory testing was conducted using micro hemagglutination (MHA-TP) assay. It was concluded that the proposed protocol for the ERHS was feasible. In addition it was found that collection of self-administered specimen and blood was acceptable.

Author:	**Tam RM. Laboratory**
Title:	**Diagnosis of Sexually Transmitted Diseases in Resource-Limited Settings**
Source:	**In Sexually Transmitted Diseases. Chapter 103, pp. 1409-20. 3rd Edition. McGraw Hill, New York; 1999**

This Chapter outlines etiologic diagnosis of STDs based on laboratory testing, clinical findings and based on syndromic management in resource limited settings. National laboratory systems typically consist of central, regional and peripheral laboratories are briefly described and their role in STD diagnosis is explained. The author outlines the resources required at each level for effective diagnosis. Concerns of microbial resistance and methods used to determine antibiotic resistance are briefly discussed. A brief summary of currently available diagnostic tests for major STDs is provided. The author emphasizes the need for additional simple, rapid and low-cost tests for developing countries and other resource-limited settings and lists priorities for STD diagnostic development.

Author:	**Wasserheit J**
Title:	**The significance and scope of reproductive tract infections among third world women**
Source:	**International Journal of Gynecology and Obstetrics 1989;30(Suppl 3):145-168**

This paper provides the reader with detailed background information on societal, physical and mental consequences that reproductive tract infections (RTI) can have on women in developing countries. Several factors central to the selection of appropriate and effective strategies for the management of RTIs in resource poor settings are reviewed. The importance of surveillance to determine the relative frequency of different RTIs and to monitor antibiotic resistance patterns of specific organisms is emphasized. Effective prophylaxis requires knowledge of the prevalence and antimicrobial sensitivities of potential pathogens in the community. In conclusion research priorities for developing countries are identified. Research must target both clinical and programmatic aspects of RTIs in reproductive health, particularly in geographical areas in which data are currently lacking. RTIs offer public health planners and clinicians a unique opportunity to improve women's health and quality of life.

Author:	**Wawer JM, Gray RH, Sewankambo NK, Serwadda D, Paxton Lynn, *et al*.**
Title:	**A randomized, community-based trial of intensive sexually transmitted disease control for AIDS prevention**
Source:	**AIDS 1998;12:1211-1225**

This article describes the design of the Rakai STD Control for AIDS prevention Study, which is an ongoing trial to test the hypothesis that intensive control of STD will result in reduced HIV infection. In order to assess whether STD control results in reduced HIV incidence biological samples were collected and analyzed. Collection methods were selected to be feasible in the field, e.g. in homes of survey respondents and to yield specimens that are stable under field conditions and amenable to processing in small field laboratories. Despite invasive specimen collection, compliance with survey and sample collections was over 90%. Recent availability of STD screening technologies that can be adapted to home-based, self-administered sample collection, i.e. urine and vaginal swabs, greatly facilitates the ability to gather representative, community-level STD data and to monitor population trends in incidence and prevalence.

Syphilis and Genital Ulcers

Bogaerts J, Vuylsteke B, Martinez-Tello W, Mekantabana V, *et al*.. Simple algorithms for the management of genital ulcers: evaluation in a primary health care centre in Kigali, Rwanda. Bulletin of the World Health Organization 1995;73(6):761-767

Ebel A, Bachelart L, Alonso JM. Evaluation of a new competitive immunoassay (BioElisa Syphillis) for screening for Treponema Pallidum antibodies at various stages of syphillis. Journal of Clinical Microbiology 1998;6(2):358-361

O'Farrell N, Hoosen AA, Coetzee KD *et al.*. Genital ulcer disease: Accuracy of clinical diagnosis and strategies to improve control in Durban, South Africa. Genitourinary Medicine 1994;70:7-11

Qiaojia H, Xiaopeng L, Tao T *et al*.. Dot-immunogold filtration assay as a screening test for syphilis. Journal of Clinical Microbiology 1996;34(8):2011-13

Reisner BS, Mann LM, Tholcken CA *et al*.. Use of the Treponema pallidum-specific captia syphilis IgG assay in conjunction with the rapid plasma reagin to test for syphilis. Journal of Clinical Microbiology 1997;35(5):1141-43

Silletti RP. Comparison of CAPTIA Syphilis G enzyme immunoassay with rapid plasma reagin test for detection of syphilis. Journal of Clinial Microbiology 1995;33(7):1829-31

Author:	**Bogaerts J, Vuylsteke B, Martinez-Tello W, Mekantabana V, *et al*.**
Title:	**Simple algorithms for the management of genital ulcers: evaluation in a primary health care centre in Kigali, Rwanda**
Source:	**Bulletin of the World Health Organization 1995;73(6):761-767**

A cross-sectional study was conducted among 395 patients presenting with genital ulcer disease (GUD) at a primary health care center in Kigali, Rwanda. Using clinical data and the results of a rapid plasma reagin (RPR) test, the authors simulated the diagnostic outcome of two flowcharts, developed by WHO for the management of GUD. These outcomes and a clinical diagnosis were then compared with the laboratory diagnosis based on culture for genital herpes and Haemophilus ducreyi and serology for syphilis. The proportion of correctly managed chancroid and/or syphilis cases was 99% using a syndromic approach, 82.1% using a hierarchial algorithm including an RPR test and 38.3% with a clinical diagnosis. In locations where syphilis and chancroid rank among the major causes of GUD and where no laboratory support is available, a simple syndromic management is superior to a clinical approach and should result in more cases being cured.

Author:	**Ebel A, Bachelart L, Alonso JM**
Title:	**Evaluation of a new competitive immunoassay (BioElisa Syphillis) for screening for Treponema Pallidum antibodies at various stages of syphillis**
Source:	**Journal of Clinical Microbiology 1998;6(2):358-361**

The BioElisa Syphilis, a new competitive enzyme immunoassay (EIA) for Treponema pallidum whole antigen that uses specific human immunoglobulin G(IgG) antibodies as the competitor, was evaluated for potential use in screening for syphilis at various stages. The results obtained by this competitive EIA were compared with those obtained by the fluorescent treponemal antibody absorption (FTA-abs) test and the T. pallidium hemaglutination assay (TPHA).
Competitive EIA had a sensitivity of 99.5% and a specificity of 99.4% relative to the results of the FTA-abs test and TPHA. The others conclude that BioElisa Syphilis is a sensitive, specific and simple assay for screening for syphilis.

Author:	**O'Farrell N, Hoosen AA, Coetzee KD *et al.***
Title:	**Genital ulcer disease: Accuracy of clinical diagnosis and strategies to improve control in Durban, South Africa**
Source:	**Genitourinary Medicine 1994;70:7-11**

The objective of this paper was to investigate the accuracy of clinical diagnosis in genital ulcer diseases (GUD) and to devise management strategies for improving the control of GUD and thereby limit the spread of HIV-1 infection.

Author:	**Qiaojia H, Xiaopeng L, Tao T *et al*.**
Title:	**Dot-immunogold filtration assay as a screening test for syphilis**
Source:	**Journal of Clinical Microbiology 1996;34(8):2011-13**

This report describes the development of a non-treponemal dot immunogold filtration assay (DIGFA) for the detection of reaginic antibody in the sera of patients with syphilis. The study findings show that the results of DIGFA were in good agreement with those of the RPR test, which is the non-treponemal test most frequently used today to detect reaginic antibody in the serum of patients with syphilis. DIGFA was simple, rapid and reproducible. The test could be completed in two minutes without the need for extra equipment. The positive dot was very obvious and the result could be easily determined with the naked eye. The results of the clinical application showed that DIGFA could be used as a routine screening method for the presumptive diagnosis of syphilis.

Author:	**Reisner BS, Mann LM, Tholcken CA *et al.***
Title:	**Use of the Treponema pallidum-specific captia syphilis IgG assay in conjunction with the rapid plasma reagin to test for syphilis**
Source:	**Journal of Clinical Microbiology 1997;35(5):1141-43**

In this paper the Captia Syphilis IgG enzyme immunoassay (EIA) is evaluated for use in conjunction with the non-treponemal rapid plasma reagin test (RPR) as a method to test for syphilis. The non-treponemal tests in general are ideal for screening large number of specimen because they are sensitive and specific and technically simple to perform. When compared to the routine protocol, the EIA-RPR protocol had sensitivity, specificity and positive predictive and negative predictive values of 96.5, 99.7, 97.3, and 99.7%, respectively. After resolution of discrepancies by additional testing the adjusted sensitivity, specificity and positive and negative predictive values were 100, 99.8, 98.3 and 100 %, respectively. This evaluation demonstrates that when used in conjunction with the RPR, the Captia Syphilis EIA is a reliable method by which to test for syphilis.

Author:	**Silletti RP**
Title:	**Comparison of CAPTIA Syphilis G enzyme immunoassay with rapid plasma reagin test for detection of syphilis**
Source:	**Journal of Clinial Microbiology 1995;33(7):1829-31**

Controversy exists as to whether an IgG immunoassay (as the Captia Syphilis G) can be used as a replacement for the non-treponemal screening tests in general and for the Reagin Plasma Response (RPR) in particular. The authors report on the ability of the Captia Syphilis G-assay to replace the RPOR test in the detection of syphilis in a large population of non-risk patients. Included into the analysis were blood specimen submitted to a laboratory from patients other than those seen at sexually transmitted disease clinics. Overall the Captia Syphilis G assay showed a sensitivity and specificity and positive and negative predictive values of 100, 98.2%, 78.9 and 100%, respectively. This was compared with an overall sensitivity and specificity and positive and negative predictive values for the RPR test of 96.4, 97.5, 72 and 99.8%, respectively. This study demonstrates that Captia Syphilis G compares favorably with the RPR test in positive and negative predictive values when used to screen for active syphilis in a low-risk population.

Chlamydia Trachomatis & Neisseria Gonorrhea

Gift TL, Pate MS, Hook E, *et al.*. The rapid test paradox: when fewer cases detected lead to more cases treated. A decision analysis of tests for chlamydia trachomatis. Sexually Transmitted Diseases 1999;26(4):232-440.

Herrmann B, Nystrom T, Wessel H. Detection of *Neisseria gonorrhoeae* from air-dried genital samples by single-tube nested PCR . Journal of Clinical Microbiology 1996;34:2548-51.

Jackson DJ, Rakwar JP, Chohan B. Urethral infection in a workplace population of East African men: evaluation of strategies for screening and management. The Journal of Infectious Diseases 1997;175: 833-888.

Lee HH, Chernskey MA, Schachter J *et al.*. Diagnosis of chlamydia trachomatis genitourinary infection in women by ligase chain reaction of urine. The Lancet 1995;345: 213-6.

Morten AN, Wakefield T, Tabrizi SN *et al.*. An outreach programme for sexually transmitted infection screening in street sex workers using self-administered samples. International Journal of STDs & HIV 1999;10:741-43.

Ohlemeyer CL, Hornberger LL, Lynch DA *et al.*. Diagnosis of Trichomonas vaginalis in adolescent females: InPouch TV Culture Versus Wet-Mount Microscopy. Journal of Adolescent Health 1998;22:205-208.

Okadome A, Notomi T, Nomura S, *et al.*. Reactivity of a dual amplified chlamydia immunoassay with different serovars of Chlamydia trachomatis. International Journal of STD & AIDS 1999;10:460-63.

Quinn TC, Welsh L, Lentz A, Crotchfeld K, *et al.*. Diagnosis by AMPLICOR PCR of Chlamydia Trachomatis infection in urine samples from women and men attending Sexually Transmitted Disease Clinics. Journal of Clinical Microbiology 1996;4(6):1401-1406.

Schachter J. DFA, EIA, LCR, and other technologies: what tests should be used for diagnosis of chlamydia infections?. Immunological Investigations 1997;26(1&2):157-161.

Tyndall MW, Nasio J, Maitha G, *et al*.. Leukocyte esterase urine strips for the screening of men with urethritis – use in developing countries. Genitourinary Medicine 1994;70:3-6.

Wessel H, Herrmann B, Dupert A. Genital infections among antenatal care attendees in Cape Verde. African Journal of Reproductive Health 1998;2(1):32-40.

Author:	**Gift TL, Pate MS, Hook E, *et al.***
Title:	**The rapid test paradox: when fewer cases detected lead to more cases treated. A decision analysis of tests for chlamydia trachomatis**
Source:	**Sexually Transmitted Diseases 1999;26(4):232-440**

The goal of this study was to determine situations, if any, in which a rapid test might be more cost-effective and treat more infections than lab-based tests. A decision analysis framework was used to compare one point-of-care test (the BioStar Chlamydia OIA) with two lab-based tests (cell-culture and the polymerase chain reaction assay). The rapid test treated more cases of infection than the PCR alone if return rate was less then 65%. A two-test algorithm of the rapid test followed by a PCR test on those initially testing negative identified and treated the greatest number of chlamydia infections and was the most cost-effective at all prevalence above 9%, but this finding was sensitive to the cost estimate of pelvic inflammatory disease. This analysis shows that a rapid test for C. Trachomatis, either alone or with another test, may be preferred for screening or diagnosis of infections in women in settings that experience a delay in communicating results and initiating therapy.

Author:	**Herrmann B, Nystrom T, Wessel H**
Title:	**Detection of *Neisseria gonorrhoeae* from air-dried genital samples by single-tube nested PCR**
Source:	**Journal of Clinical Microbiology 1996;34:2548-51**

This paper describes a highly sensitive single tube nested PCR method for the detection N. gonorrhea. The method was used on air-dried samples kept for up to one year under different storage conditions and was compared with a commercial PCR assay for genital samples from women in Cape Verde. Results demonstrate that this sensitive nested PCR assay, combined with air-dried storage, allows for the detection of gonococci when specimen storage and transport times are extended and freezing conditions are not available.

Author:	**Jackson DJ, Rakwar JP, Chohan B**
Title:	**Urethral infection in a workplace population of East African men: evaluation of strategies for screening and management**
Source:	**The Journal of Infectious Diseases 1997;175:833-888**

The purpose of this study is to evaluate potential strategies for the screening and management of urethral infection in men, with emphasis on the urine esterase leukocyte dipstick (LED) test. An attempt is made to identify demographic and behavioral risk factors that could provide guidance in the development of risk scores for screening purposes. The urine LED test, which identifies pyuria, is relatively inexpensive and has shown promise as a screening tool to identify N. Gonorrhea and C. trachomatis infections. In this study transport workers in Mombasa, Kenya were screened for urethral infection by history, clinical examination and laboratory testing of urethral swabs and first catch urine specimen. A positive LED test on urine predicted infection with a sensitivity and specificity of 95.0% and 59.3%, respectively in symptomatic men and 55.3% and 82.8%, respectively in asymptomatic men. Despite the low sensitivity and specificity of the results the LED test currently appears to be the best-performing available screening method for resource poor settings, especially in situation where quick results are needed.

Author:	**Lee HH, Chernskey MA, Schachter J *et al.***
Title:	**Diagnosis of chlamydia trachomatis genitourinary infection in women by ligase chain reaction of urine**
Source:	**The Lancet 1995;345:213-6**

The authors compared a ligand chain reaction (LCR) based assay to detect Chlamydia trachomatis plasmid DNA in first void urine samples with culture of endocervical swabs for matched specimens from women from four geographical regions. The sensitivity and specificity of the LCR assay with first void urine samples compared with an expanded gold standard were 93.8% and 99.9% respectively. The LCR assay was highly effective for the detection of chlamydia trachomatis in urine from women with or without signs or symptoms of chlamydia genitouriary tract infections. Previous methods of detecting chlamydia trachomatis infection required swabbing of urethral or endocervical sites. This method of specimen collection can be painful and uncomfortable. The lower costs and greater acceptability of urine testing are an important consideration for screening programs.

Author:	**Morten AN, Wakefield T, Tabrizi SN *et al.***
Title:	**An outreach programme for sexually transmitted infection screening in street sex workers using self-administered samples**
Source:	**International Journal of STDs & HIV 1999;10:741-43**

This paper describes a cross-sectional study of street sex workers in Melbourne, Australia using a self-administered method to detect chlamydia, gonorrhea and trichomonas infections. Comparative data was collected from brothel sex workers attending the main sexual health clinic in Melbourne. Women's specimen were collected through self-inserted tampons which were placed into a transport medium immediately after collection. Men were asked to give first passed urine. Samples from street workers were brought to a laboratory and analyzed for Neisseria gonorrhea, Trichomonas vaginalis and Chlamydia trachomatis by Polymerase Chain Reaction (PCR). Samples positive for N. gonorrhea were confirmed using Roche Amplicor kit and sequenced using Prism cycle sequencekit. Results demonstrate that this method of testing for STIs was acceptable to street sex workers and showed that this type of outreach program can have a high yield with regard to asymptomatic infection in this group.

Author:	**Ohlemeyer CL, Hornberger LL, Lynch DA *et al.***
Title:	**Diagnosis of Trichomonas vaginalis in adolescent females: InPouch TV Culture versus Wet-mount Microscopy**
Source:	**Journal of Adolescent Health 1998;22:205-208**

The purpose of this study was to compare the InPouch TV culture to wet-mouth, Diamond's culture medium, and Papanicolaou (Pap) smear for the diagnosis of trichomonas infection in sexually active adolescents. 12-18 year old girls who received pelvic examinations were recruited from urban adolescent clinics. Results showed that InPouch TV cultures have a higher sensitivity than wet-mount microscopy. Advantages of InPouch TV cultures include that it produces reliable results in less time than the standard culture method and it has fewer problems with contaminating microorganisms. The Pouch itself has a long shelf-life and is inexpensive. InPouch TV culture is an excellent alternative to traditional culture media in diagnosing trichomonas infection in adolescent females.

Author:	**Okadome A, Notomi T, Nomura S, *et al.***
Title:	**Reactivity of a dual amplified chlamydia immunoassay with different serovars of Chlamydia trachomatis**
Source:	**International Journal of STD & AIDS 1999;10:460-63**

A study was undertaken with different serovars (D, E, F, L2, MoPn) of Chlamydia trachomatis to determine the analytical sensitivity of a new dual amplified immunoassay (IDEIA PCE Chlamydia) for detecting chlamydial lipopolysaccharide. IDEIA PCE Chlamydia incorporates a polymer conjugate consisting of multiple copies of antibody and enzyme molecules to provide signal amplification. The test was also assessed with different protein A producing strains of staphylococcus aureus in order to assess whether the use of a multiple antibody conjugate increased nonspecific binding. The incorporation of the polymer conjugate resulted in a 2-5 fold increase in analytical sensitivity compared to an earlier version of the test using a conventional conjugate. No increase in cross-reactivity with protein A producing strains of S. aureus was obtained. The new dual amplified test format offers potential as a sensitive low-cost screening assay for C. trachomatis.

Author:	**Quinn TC, Welsh L, Lentz A, Crotchfeld K, *et al.***
Title:	**Diagnosis by AMPLICOR PCR of Chlamydia Trachomatis infection in urine samples from women and men attending sexually transmitted disease clinics**
Source:	**Journal of Clinical Microbiology 1996;4(6):1401-1406**

In the past screening of C. Trachomatis required the collection of endocervical swab specimen and urethral swab specimen for women and men, respectively. This study evaluates AMPLICOR C. Trachomatis, a commercially available Polymerase Chain Reaction (PCR) assay for the detection of C. Trachomatis using urine samples from women and men attending STD clinics in the United States. In order to determine the sensitivity and specificity of this PCR assay the authors compared urine samples from men and women with those of culture of urethral and endocervical swab specimen. The resolved sensitivity and specificity of urine PCR for men was 88% and 97%, respectively and for women it was 93% and 98%, receptively. Additional advantages of urine-based screening include the ease of sample collection, simple transports and storage requirements and the avoidance of sampling bias during urethral and endocervical examination. Urine based screening provides a non-invasive screening method of both symptomatic and asymptomatic patients.

Author:	**Schachter J**
Title:	**DFA, EIA, LCR, and other technologies: what tests should be used for diagnosis of chlamydia infections?**
Source:	**Immunological Investigations 1997;26(1&2):157-161**

This paper reviews various technologies available for diagnosis of chlamydia infections and discusses factors influencing the decision of which test to use. For many years isolation in tissue culture (TC) was considered the test of choice for diagnosis of Chlamydia trachomatis infection. Non-culture tests, such as direct fluorescent antibody (DFA) and enzyme immunoassay (EIA) which detected chlamydial antigens in clinical specimens, made chlamydia diagnostic tests more widely available. It is only with the introduction of amplified DNA tests [polymerase chain

reaction (PCR) and ligase chain reaction (LCR)] that non-culture tests became available that were actually more sensitive than TC. Until there is a fairly sophisticated cost-benefit analysis or a change in the pricing of these tests, it seems obvious that TC will remain the best choice where medical/legal implications are important. DFA will probably remain a widely used test for laboratories that process relatively small numbers of specimens and EIAs will play a role where cost is a major factor and large number of specimens require bulk processing. Where they are affordable, the amplified DNA tests are to be preferred as they are far more sensitive than these other non-culture tests.

Author:	**Tyndall MW, Nasio J, Maitha G, *et al*.**
Title:	**Leukocyte esterase urine strips for the screening of men with urethritis – use in developing countries**
Source:	**Genitourinary Medicine 1994;70:3-6**

This study was conducted to evaluate the preformance of the Leukocyte esterase (LE) Dipstick in Nairobi, Kenya, where STDs are common and resources limited. First void urine was collected for LE dipstick testing. Results of the dipstick were compared with the laboratory detection of Chlamydia trachomatis (CT) and Neisseria gonorrhea (NG) using PCR. Esterase activity had a sensitivity and specificity of 96 and 80%, respectively and positive and negative predictive values of 42 and 94%, respectively for the presence of CT and NG. In settings with severely limited resources the LE dipstick is a useful tool for screening of men with urethritis. The LE dipstick has great potential in aiding decisions regarding antibiotic use in men with urethritis.

Author:	**Wessel H, Herrmann B, Dupert A**
Title:	**Genital infections among antenatal care attendees in Cape Verde**
Source:	**African Journal of Reproductive Health 1998;2(1):32-40**

This article describes a cross-sectional study to determine prevalence of Chlamydia trichomonas (CT), Neisseria gonorrhea (NG) and of Bacterial vaginosis (BV) among antenatal care clients in Praia, Cape Verde. To assess the validity of currently used microbiological analysis in Praia, clinical specimen were tested using different methods of specimen preparation and different diagnostic methods. For example, endocervical specimen were collected using non-toxic cotton tipped aluminum swabs to detect CT, by direct immunoflourescence technique on glass slides and other endocervical sample were air-dried on a slide to detect CT using the PCR system Amplicor. Among various analytical methods used, the polymerase chain reaction (PCR) for NG and CT yielded a higher detection rate than did direct microscopy or culture (NG) or direct immunoflourescence (CT). Since the PCR analytic is not hampered by harsh storage and transport conditions, it could serve to validate other detection methods where laboratory facilities are suboptimal.

Other RTI/STIs

Anderson CM, Nottingham J. Bridging the knowledge gap and communicating uncertainties for informed consent in cervical cytology screening: we need unbiased information and a culture change. Cytopathology 1999;10:221-228

Cox JT, Lorincz AT, Schiffman MH, *et al*.. Human Papillomavirus testing by hybrid capture appears to be useful in triaging women with cytologic diagnosis of atypical squamous cells of undetermined significance. American Journal of Obstetrics and Gynecology 1999;172(3):946-954

Kuypers JM, Critchlow CW, Gravitt PE, *et al.*. Comparison of dot filter hybridization, southern transfer hybridization and polymerase chain reaction amplification for diagnosis of anal human papillomavirus. Journal of Clinical Microbiology 1993;31(4):1003-06

Nugent RP, Krohn MA, Hillier SL. Reliability of diagnosing bacterial vaginosis is improved by a standardized method of Gram-stain interpretation . Journal of Clinical Microbiology 1991;29(2):297-301

Sedlacek TV. Advances in the diagnosis and treatment of Human Papilomavirus infections. Clinical Obstetrics and Gynecology 1999;42(2):206-220

Swaddiwudhipong W, Chaovakiratipong C, Nguntra P, *et al.*. A mobile unit: an effective service for cervical screening among rural Thai women. International Journal of Epidemiology 1999;28:35-39

Trofatter KF. Diagnosis of Human papillomavirus genital tract infections. The American Journal of Medicine 1997;102(5A):21-26

Troungos C, Horti M, Kittas C. A rapid method for the screening and typing of high risk HPVs using molecular biology techniques. Anticancer Research 1995;15:2045-48

Waldhuber MG, Denham I, Wadey C. Detection of herpes simplex virus in genital specimens by type-specific polymerase chain reaction. International Journal of STDs & AIDS 1999;10:89-92

Author:	**Anderson CM, Nottingham J**
Title:	**Bridging the knowledge gap and communicating uncertainties for informed consent in cervical cytology screening: we need unbiased information and a culture change**
Source:	**Cytopathology 1999;10:221-228**

The objective of this paper is to endorse recent recommendations that women need honest information for informed consent to screening. Surveys continue to show that in cervical screening women do not have enough information. Methods of obtaining informed consent and possible ways of how the knowledge gap between experts and the general public can be narrowed are reviewed. The need for authoritative unbiased information sheets, for discussion with women before the smear, and for briefing politicians, lawyers, journalists and the general public is emphasized. An information strategy is proposed, which may not be cheap but should pay off in terms of litigation averted.

Author:	**Cox JT, Lorincz AT, Schiffman MH, *et al*.**
Title:	**Human Papillomavirus testing by hybrid capture appears to be useful in triaging women with cytologic diagnosis of atypical squamous cells of undetermined significance**
Source:	**American Journal of Obstetrics and Gynecology 1999;172(3):946-954**

The purpose of this study was to determine the clinical value of human papillomavirus DNA testing with the hybrid capture test. It was examined whether human papillomavirus (HPV) testing could identify which women with Papanicolaou (pap) smears read as atypical squamous cells of undetermined significance were most likely to have histologically confirmed cervical intraepithelial neoplasia. The sensitivity of hybrid capture for any cervical intraepithelial neoplasia was 86% and for grade 2 or 3 was 93%, whereas the corresponding values for the pap smear were 60% and 73%, respectively. This study demonstrated that HPV DNA testig with hybrid capture can be used to triage women with a cytologic diagnosis of atypical squamous cells of undetermined significance.

Author:	**Kuypers JM, Critchlow CW, Gravitt PE, *et al.***
Title:	**Comparison of dot filter hybridization, southern transfer hybridization and polymerase chain reaction amplification for diagnosis of anal human papillomavirus**
Source:	**Journal of Clinical Microbiology 1993;31(4):1003-06**

The detection and classification of human papillomavirus (HPV) by Polymerase Chain Reaction (PCR) were compared with detection and classification by dot filter hybridization (DFH) and Southern transfer hybridization (STH). Anal epithelial cell samples were collected from homosexual men enrolled in a study of anal squamous intraepithelial lesion. PCR detected HPV in 87% of specimens. The detection rates for DFH and STH were 51 and 49%, respectively. The specific HPV types detected by STH were also detected by PCR in 90% of specimens. PCR results were reproducible, as assessed by repeat analysis, by analysis of paired same-day specimens and by interlaboratory analysis. PCR is a sensitive, specific and reproducible test for HPV detection and classification in clinical and epidemiological studies.

Author:	**Nugent RP, Krohn MA, Hillier SL**
Title:	**Reliability of diagnosing bacterial vaginosis is improved by a standardized method of Gram-stain interpretation**
Source:	**Journal of Clinical Microbiology 1991;29(2):297-301**

The purpose of this study was to examine intercenter variability in the interpretation of Gram-stained vaginal smears from pregnant women. The intercenter reliability of individual morphotypes identified on the vaginal smear, obtained from cohorts of women at five centers, was evaluated by comparing them with those obtained at a standard center. A new standardized scoring system that uses the most reliable morphotypes from the vaginal smear was proposed for diagnosing bacterial vaginosis. This scoring system was compared with the Spiegel criteria for diagnosing bacterial vaginosis (BV). The standardized score had improved intercenter reliability compared with the Spiegel criteria. The standardized score also facilitates future research concerning BV because it provides gradations of the disturbance of vaginal flora which may be associated with different levels of risk for pregnancy complications.

Author:	**Sedlacek TV**
Title:	**Advances in the diagnosis and treatment of Human Papilomavirus infections**
Source:	**Clinical Obstetrics and Gynecology 1999;42(2):206-220**

The purpose of this paper is to review current information on HPV and to attempt to develop rational evidence-based programs. This article provides excellent background to Human Papillomavirus (HPV) characteristics, risk factors for HPV infections, malignant transformation and the immune systems' response to HPV. Papinocolaou (pap) smear is described as the most cost-effective indicator as HPV infection. Since 1995 three new techniques to improve pap smear accuracy have been approved for clinical use by the Food and Drug Administration (FDA). Cervicography is mentioned as another diagnostic method, which captures a photographic image of the acetic acid treated cervix for later review by a trained interpreter. An extensive list of treatment methodologies is also provided in the text. New treatment programs rely on drugs that modulate the immune system and disrupt viral persistence.

Author:	**Swaddiwudhipong W, Chaovakiratipong C, Nguntra P, *et al.***
Title:	**A mobile unit: an effective service for cervical screening among rural Thai women**
Source:	**International Journal of Epidemiology 1999;28:35-39**

This study evaluates the effect of a systematic screening program for cervical cancer, using a mobile unit, in rural Thailand. The purpose of using the mobile unit was to increase knowledge and use of Papanicolaou (pap) smear among rural Thai women. To evaluate the programs' effect on changes in knowledge and use, results of three interview surveys of women, conducted at baseline and at follow-up, were compared. Results of data taken by the mobile unit were compared with other existing screening services in the study area. Both knowledge and use of Pap smear were found to be increased. Screening by the mobile unit accounted for 85.2% of all cervical intraepithelial neoplasia and all invasive cancers identified among the Pap smears taken by screening services in the area between 1992 and 1996. The use of a mobile unit may be an effective screening program in rural areas where existing screening activities cannot effectively reach the female population at risk.

Author:	**Trofatter KF**
Title:	**Diagnosis of Human papillomavirus genital tract infections**
Source:	**The American Journal of Medicine 1997;102(5A):21-26**

This paper briefly describes conventional methods for diagnosis of HPV infection and DNA tests for detecting the type of HPV infection. Information on sensitivity, specificity and disadvantages of each test is provided. Conventional tests reviewed are visual inspection, colposcopy or cervicography, papinocolaou (pap) smear and serology. Tests that detect the presence of HPV DNA are Southern Blot, dot blots, in situ hybridization, filter in situ hybridization, PCR and hybrid capture assay. The author mentions that HPV DNA plays an important role in triaging patients whose pap smear show a typical squamous cells of undetermined significance. However, HPV DNA assays are not yet practical for routine screening, partly because these tests are often labor intensive and expensive.

Author:	**Troungos C, Horti M, Kittas C**
Title:	**A rapid method for the screening and typing of high risk HPVs using molecular biology techniques**
Source:	**Anticancer Research 1995;15:2045-48**

This paper describes a rapid method for the screening and typing of high risk HPVs in clinical specimen using Polymerase Chain Reaction (PCR). Given its high degree of sensitivity and specificity the PCR, which can detect very low DNA amount, has proved to be particularly useful for the detection of HPV types with known DNA sequences from small amounts of tissue specimen. The typing of the high risk HPV is achieved by restriction enzyme analysis using the endonuclease Alu I which cleaves each high risk HPV type at different sites, thus permitting the distinction of high and low risk HPV types and the identification of each type of the high risk group.

Author:	**Waldhuber MG, Denham I, Wadey C**
Title:	**Detection of herpes simplex virus in genital specimens by type-specific polymerase chain reaction**
Source:	**International Journal of STDs & AIDS 1999;10:89-92**

This study describes the development of a type-specific polymerase chain reaction (PCR) assay for detection and typing of HSV-1 and HSV-2, and a comparison of its sensitivity with that of isolation in a clinical setting. Specimens from patients presenting with genital ulcers were tested for the presence of HSV by both methods. Detection by PCR has 2 major advantages over virus isolation. Firstly, samples for testing by PCR require less vigorous storage conditions than those required for virus isolation. Secondly, in the context of HSV, PCR has been shown to be more sensitive than isolation. When compared with OCR detection of HSV by isolation had a sensitivity and specificity of 67 and 97%, respectively. This study has shown the PCR to be a rapid, sensitive and specific alternative to culture for the detection of HSV in clinical specimen.