

Overview of changing happening to laboratory testing at Texas Department of State Health Services (DSHS), effective September 1, 2013

Testing

Effective September 1, 2013 the tests listed below are no longer offered by the DSHS. Most of these tests were discontinued due to low volume of submitted samples. A “low volume test” is one that was ordered less than 100 times in 2011, not considered a core public health test by the department, and readily available from commercial laboratories.

- Cholera, culture confirmation
- Phenylketonuria (PKU) Full Gene Sequencing
- Aspergillus
- Legionella
- Fungal identification (blastomycosis, coccidioidomycosis, histoplasmosis)
- Fungal panel (blastomycosis, coccidioidomycosis, histoplasmosis)
- Hepatitis BeAG
- Hepatitis BeAb
- Bottled Water
- Fecal coliforms, multiple tube fermentation (MFT)
- Reagent water suitability
- HIV 1,2,plus 0 Screen (was replaced by HIV combo Ag/Ab EIA testing see HIV information)
- HDN testing which includes Antibody identification, and Antibody titer (see additional information below regarding HDN testing)

Prenatal HDN testing is no longer sent to DSHS Austin Laboratory. The HDN testing must be sent to a laboratory of provider’s choice.

The following HDN testing codes and reimbursement rates were added to the FY13 Title V MCH Monthly Voucher and Report (Prenatal and Prenatal/Post-partum Dental) – Revised 05/2013:

- CPT Code 86850 – Blood, antibody screen will be reimbursed at \$7.70
- CPT Code 86900 – Blood Typing, ABO will be reimbursed at \$4.23
- CPT Code 86901 – Rh Typing will be reimbursed at \$4.23

The “Revised 05/2015” monthly voucher became effective May 1, 2013. The revised monthly voucher is located at: http://www.dshs.state.tx.us/chscontracts/all_forms.shtm#titleVfee.

For any questions, please contact Joan Aalbers at 512-776-2094 or email joan.aalbers@dshs.state.tx.us.

Effective September 1, 2013, the tests listed below are new tests offered by DSHS.

- Gonorrhea/Chlamydia (GC/CT)- GC/CT, amplified RNA Probe--\$20.28
- GC culture confirmation by amplified or direct probe--\$37.66
- GC Screen---\$44.54
- Vibrio--\$228.15
- Lewisite metabolites in urine (2-chlorovinylarsonous acid (CVAA) and 2-chlorovinylarsonic acid (CVAOA), liquid chromatography, inductively coupled plasma mass spectrometry (LC-ICP-MS)--\$157.59
- MGIT drug susceptibility test, primary panel--\$115.05
- MGIT PZA susceptibility test--\$77.17
- Amino Acid Dietary Monitoring--\$16.61
- Arbovirus identification, PCR: West Nile virus--\$57.87
- Dengue, real-time, PCR--\$215.52
- Influenza pyrosequencing for antiviral resistance--\$13.11
- Measles, real-time PCR--\$126.83
- Mumps, real-time PCR--\$127.83
- Respiratory viral panel, PCR--\$167.13
- Cronobacter sakazakii--\$115.17
- Non-0157 STEC--\$295.02
- West Nile Virus (WNV), Mosquitoes, PCR--\$57.87
- Drinking water-trihalomethanes, EPA Method 551.1--\$43.91
- Food- Gluten\$90.97
- HIV combo Ag/Ab EIA --\$7.90 (Testing algorithm for HIV has changed see details below under HIV section)
- Syphilis: Screening, IgG--\$7.57 (Testing algorithm for syphilis has changed see details below under syphilis section)

FEES

Senate Bill 80 of the 82nd Texas Legislative session enacted law that states the laboratory must analyze the laboratory cost for testing and update fees as needed. As part of this legislative mandate, the DSHS Laboratory must adjust fees to ensure that the laboratory is charging a fee that is equal to the cost the laboratory incurs for that testing. Effective September 1, 2013 the following pricing adjustment have been made.

Price reduction

- Haemophilus: culture confirmation, serological, fee reduced from \$138.64 to \$91.58
- Nucleic Acid Amplification for Mycobacterium Tuberculosis(M. Tuberculosis), fee reduced from \$197.41 to \$166.70
- Cytomegalovirus (CMV) IgG, fee reduced from \$399.97 to \$23.23
- Cytomegalovirus (CMV) IgM, fee reduced from \$161.02 to \$24.26
- Hepatitis A: IgM, fee reduced from \$317.74 to \$44.04
- Hepatitis A: total, fee reduced from \$219.60 to \$34.45
- Hepatitis B: core antibody, fee reduced from \$143.90 to \$36.06
- Hepatitis B: core IgM antibody, fee reduced from \$295.64 to \$44.75
- Hepatitis B: surface antibody (Ab), fee reduced from \$103.84 to \$28.34
- Hepatitis B: surface antigen (Ag), fee reduced from \$51.45 to \$18.47
- Mumps: Epidemic parotitis IgG, fee reduced from \$154.46 to \$22.62
- QuantiFERON (tuberculosis serology) , fee reduced from \$84.45 to \$53.66
- Rubella: IgM , fee reduced from \$329.37 to \$24.77
- Rubella: screen , fee reduced from \$24.13 to \$22.33
- Rubeola: screen (IgG), fee reduced from \$165.16 to \$21.35
- Toxoplasmosis, fee reduced from \$357.49 to \$23.23
- Varicella Zoster Virus, (VZV), fee reduced from \$345.63 to \$19.70
- Food-Mercury, EPA method 245.1 and EPA SW-846 methods 7470A and 7471B, fee reduced from \$192.35 to \$37.90
- Soils and solids- mercury, sediment, EPA SW-846 method 7471B, fee reduced from \$194.22 to \$37.90
- Tissue-Fillets, fee reduced from \$34.56 to \$19.98
- Tissue-mercury, EPA method 7471B, fee reduced from \$192.35 to \$37.90

Name changes to testing for clarification purposes and price reduction in fee occurred for the tests listed below.

- Aerobic culture from clinical specimen will be renamed to Aerobic Isolation from clinical Specimen and price will be reduced from \$367.37 to \$303.92
- Anaerobic culture from clinical specimen will be renamed to Anaerobic isolation from clinical specimen and price will be reduced from \$197.10 to \$118.39

- Neisseria meningitides will be renamed to Neisseria and price will be reduced from \$390.52 to \$141.84
- Influenza (typing, PCR) will be renamed to Influenza surveillance without culture (typing PCR) and price will be reduced from \$248.00 to \$131.32

Price increase

- Non-potable water-single metal, ICP, EPA method 200.7 and EPA SW-846 method 6010C fee increased from \$67.49 to \$114.04
- Pertussis , polymerase chain reaction will be renamed to Bordetella pertussis, Parapertussis, and Bordetella holmesii polymerase chain reaction (PCR) and the price will increase from \$32.11 to \$213.79.

New service charges for specimens handling were added to the fee schedule.

- Special specimen processing and storage of clinical specimens--\$25.00
- Preparation and storage of composite samples for chemical analysis--\$19.23

A fee for each Phenylalanine / Tyrosine Dietary Monitoring test will be charged at \$16.61. If patient insurance or Medicaid information is not provided, the submitter will be billed for the test. Please note that the current version of the G1B test request form contains 'NBS Case Management' as a selection option under Payer Source. This is not a valid option. Submitters who select this option will be billed the appropriate fee.

Changes to Title V laboratory testing

Effective September 01, 2013, Title V fee-for-service (FFS) contractors may send Title V laboratory testing specimens to the laboratory of the contractors' choice. FFS contractors will no longer be required to submit covered Title V laboratory testing to the DSHS Laboratories.

Due to this program change, the DSHS Laboratories will be removing the following Title V program categories from the DSHS Laboratory Submission forms which were located in the Payer Source Box of each DSHS Laboratory Submission form:

- Title V Child Health and Dental
- Title V Prenatal
- Title V Family Planning
- Title V Dysplasia

Revised DSHS Laboratory Submission forms will be distributed in the summer of 2013, in preparation for this change and also to accommodate testing menu changes being made as part of the ongoing DSHS Laboratory Fee Schedule revision.

Please be aware that effective September 1, 2013, Title V FFS contractors will be billed for all DSHS Laboratory testing services and payment will be due to the DSHS Laboratory from the Title V FFS contractor who ordered the laboratory testing service. Title V FFS contractors who wish to continue to use the testing services of the DSHS Laboratories can continue doing so using their existing laboratory submitter number(s).

The DSHS Laboratories fee schedules may be found using the following links:

- Austin DSHS Laboratory Fee Schedule:

<http://www.dshs.state.tx.us/lab/fees.shtm>

- STL DSHS Laboratory Fee Schedule:

http://www.dshs.state.tx.us/lab/so_tx_lab.shtm

Title V program laboratory tests will be noted in the Prenatal and Child Health Chapters in the Policies and Procedures Manual for Title V Maternal & Child Health Fee-for-Service for Child Health, Dental and Prenatal located at: <http://www.dshs.state.tx.us/mch/fee/pandp.shtm>. The laboratory tests will also be listed on the Monthly Reimbursement Request for reimbursement located at: http://www.dshs.state.tx.us/chscontracts/all_forms.shtm#titleVfee.

For allowable program-covered laboratory testing questions, please contact Joan Aalbers, Maternal and Child Health Nurse Consultant, at 512-776-2094 or joan.aalbers@dshs.state.tx.us or visit www.dshs.state.tx.us/mch/fee/pandp.shtm.

Other Changes

Changes to the naming of tests to more accurately reflect the actual procedure also occurred in the update.

- Culture: Clinical will be renamed to Culture: Supplemental Cell Culture
- Influenza culture will be renamed to Influenza Surveillance with culture
- Viral agent: isolation will be renamed viral agent: viral isolation, clinical

Changes to HIV testing

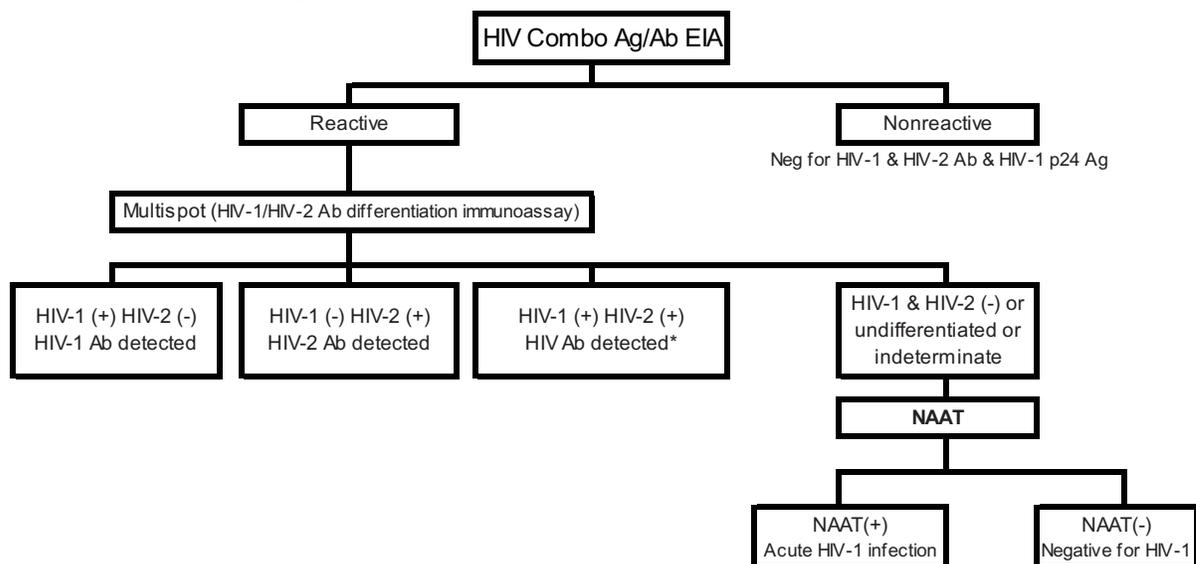
The DSHS Laboratory in Austin will be using the new HIV diagnostic testing algorithm. HIV screening is performed by the 4th generation HIV Combo Ag/Ab EIA test for HIV detection. Results of this test do not distinguish between the presence of HIV antibodies or antigen in a sample. Additional supplemental tests will be automatically performed to verify the presence of antibodies to HIV-1 or HIV-2 by Multispot HIV-1/HIV-2 rapid test and HIV-1 p24 antigen by Nucleic Acid Amplification Test (NAAT) performed by the Dallas Co. Dept. Of Health and Human Services at: 2377 N. Stemmons Freeway, Dallas TX 75207, CLIA # 45D0672012. A single HIV report will be released with interpretation guidelines. **The serum specimen acceptance criteria for the testing will not change.**

Third- and fourth-generation HIV immunoassays are important advances for HIV testing that improve the ability to detect HIV infections earlier. In the two prospective evaluations described in MMWR (1), the new diagnostic testing algorithm performed better than the current algorithm for identifying HIV infections. With FDA's approval of the Multispot HIV-1/HIV-2 rapid test for use as the second test in this algorithm in March 2013, laboratories can adopt this algorithm, which is a recommended option in the Clinical and Laboratory Standards Institute's (CLSI) Criteria for Laboratory Testing and Diagnosis of HIV Infection; Approved Guideline (2).

HIV-1 Western Blot (WB) for serum samples will be available for reference testing purposes only. NAAT will be performed only as a follow up testing for the HIV screening using the new HIV diagnostic testing algorithm and will not be offered as a standalone test at the DSHS Laboratory.

Questions should be directed to the HIVSTD Serology Team at 512-776-7657.

New HIV diagnostic testing algorithm



* Additional testing required to rule out dual infection with HIV-1 and HIV-2.

HIV Screening, multispot HIV-1/HIV-2 rapid test, and NAAT results interpretation:

HIV Combo Ag/Ab EIA	Multispot	Interpretation
Nonreactive	<i>(not performed)</i>	No serologic evidence of infection with HIV. Cannot exclude incubating or early HIV infection. Submit second sample in 3-4 weeks if clinically indicated.
Reactive	HIV-1	Presumptive evidence of HIV-1 infection: Based on EIA and MS HIV-1 Ab positive results, probable active HIV-1 infection. (NAAT is not indicated per CLSI guidelines). Refer to physician for care.
Reactive	HIV-2	Presumptive evidence of HIV-2 infection: Based on EIA and MS HIV-2 Ab positive results, probable active HIV-2 infection. (NAAT is not indicated per CLSI guidelines). Refer to physician for care.
Reactive	Nonreactive or Indeterminate / Undifferentiated	Possible acute infection: Based on EIA and MS results, possible acute HIV infection (AHI). Test for NAAT to rule out AHI; if reactive, possible AHI. Refer to physician for care. If NAAT is nonreactive or not tested, submit second sample in 3-4 weeks to rule out HIV infection with HIV-1 or HIV-2.

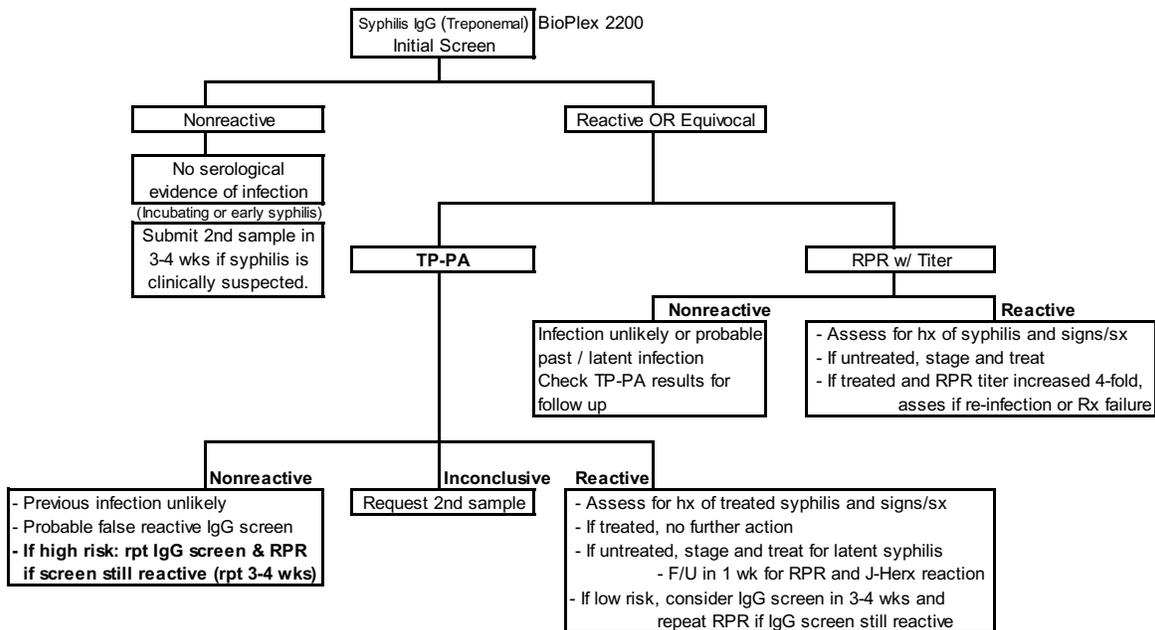
1. Detection of Acute HIV Infection in Two Evaluations of a New HIV Diagnostic Testing Algorithm — United States, 2011–2013. [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6224a2.htm?s_cid=mm6224a2_e\[7/15/2013 1:08:43 PM\]](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6224a2.htm?s_cid=mm6224a2_e[7/15/2013 1:08:43 PM])
2. Clinical and Laboratory Standards Institute. Criteria for laboratory testing and diagnosis of human immunodeficiency virus infection; approved guideline. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

Change in syphilis testing

Effective September 1, 2013, the DSHS Laboratory in Austin will no longer be using the RPR as the syphilis screening test. The RPR screen will be replaced with the *Treponema pallidum* (*T. pallidum*) IgG EIA test following Reverse Syphilis Algorithm. Please order **Syphilis, Screening IgG (per G2A form)** when syphilis screening is needed. The IgG test will be performed daily (Monday-Friday). If the IgG test is reactive the reflex RPR Qualitative with titer and TP-PA testing will be performed on the same day or next day and a single report will be released with interpretation guidelines. The serum specimen acceptance criteria for the testing will not change.

T. pallidum IgG EIA has equal sensitivity and greater specificity than RPR, which detects anticardiolipin antibodies. The IgG test remains positive for many years following eradication of the disease. Therefore, the RPR test is essential to demonstrate active disease, to monitor therapy, detect treatment failure, and re-infection. RPR standalone test with titer will be available for treatment follow up. TP-PA standalone test will be available for confirmation of RPR results performed by other laboratories. FTA-ABS test will not be used to confirm discordant treponemal screening results per CDC recommendations and will be discontinued at the DSHS Laboratory.

This new algorithm is commonly used in laboratories and is included in the Centers for Disease Control and Prevention STD screening guidelines (1, 2). Questions should be directed to the HIVSTD Serology Team at 512-776-7657.



BioPlex 2200 Syphilis IgG, TP-PA IgG, and non-treponemal RPR results interpretation:

Syphilis IgG	RPR_QUAN	TP-PA	Interpretation
Nonreactive	(not performed)	(not performed)	No serologic evidence of infection with <i>T. pallidum</i> . Cannot exclude incubating or early syphilis. Submit second sample in 3-4 weeks if clinically indicated.
Reactive/Equivocal	Nonreactive	Reactive	Probable past or latent infection: Based on IgG, RPR, and TPPA results, probable past or treated or latent infection with <i>T. pallidum</i> .
Reactive/Equivocal	Nonreactive	Nonreactive	<i>T. pallidum</i> infection unlikely: Based on IgG, RPR, and TPPA results, previous <i>T. pallidum</i> infection unlikely. Submit second sample in 3-4 weeks if clinically indicated.
Reactive/Equivocal	Nonreactive	Inconclusive	Request second sample: Based on IgG, RPR, and TPPA results, a second sample should be sent. Repeat testing in 3-4 weeks if high risk of acquiring syphilis infection.
Reactive/Equivocal	Reactive (1:X)	Reactive	Presumptive evidence of current infection: Based on IgG, RPR, and TPPA results, probable active <i>T. pallidum</i> infection.
Reactive/Equivocal	Reactive (1:X)	Nonreactive	Possible infection with <i>T. pallidum</i> or biological false positive: Based on IgG, RPR, and TPPA results, possible infection or biological false positive. Submit second sample in 3-4 weeks if clinically indicated.
Reactive/Equivocal	Reactive (1:X)	Inconclusive	Request second sample: Based on IgG, RPR, and TPPA results, a second sample should be sent for repeat testing in 3-4 weeks.

3. CDC. STD treatment guidelines 2006. Morbid Mortal Wkly Rep 2006;55(RR-11):1-94.
4. Pope V. Use of treponemal tests to screen for syphilis. Infect Med 2004;21:399-402.

South Texas Laboratory

New tests added at the South Texas Laboratory

- Gram Stain—\$8.06
- Urine culture—\$11.59
- Alanine Amino Transferase (ALT)—\$1.34
- Bilirubin, Direct—\$1.69
- Bilirubin, total & Direct profile—\$2.44
- Glucose—\$1.34
- Biological Threat refernece culture—\$198.28
- Definitive Identification: Bacillus Anthracis—\$145.72
- Definitive Identification: Brucella species—\$214.30
- Definitive Identification: Burkholderia—\$221.62
- Definitive Identification: Francisella tularensis—\$107.07
- Definitive Identification: Yersinia pestis—\$313.47
- Definitive Identification: Unknown biological threat agent—\$220.08
- Food samples: Bacillus Anthracis—\$23.77
- Food samples: Brucella species—\$25.77
- Food samples: E.coli 0157:H7—\$7.15
- Food samples: Francisella—\$17.20
- Food samples: Listeria—\$21.30
- Food samples: Salmonella—\$19.05
- Food samples: Yersinia pestis—\$313.47
- PCR: Bacillus Anthracis—\$58.41
- PCR:Brucella—\$58.41
- PCR: Burkholderia—\$58.41
- PCR: Francisella tularensis—\$58.41
- PCR: Influenza—\$51.26
- PCR: Influenza A—\$53.63
- PCR: Influenza A/H5, PCR—\$125.00
- PCR: Multiple Agent Panel—\$169.39
- PCR: Ricin—\$150.00
- PCR: Yersinia pestis—\$58.41
- Peripheral Smear Review—\$7.59
- MGIT susceptibility (each drug), PZA—\$92.69
- Identification of AFB isolate, DNA probes—\$44.63
- Thyroxine (T4), free—\$10.89
- Thyroid Hormone (T3) uptake—\$23.67
- Random Urine/Creatinine Profile—\$6.44
- Urine Microscopic Analysis—\$5.54

Price reduction

- Conventional susceptibility (each drug), Fee reduced from \$36.45 to \$14.06
- MGIT susceptibility (each drug), Fee reduced from \$92.69 to \$43.47

Name changes to tests at STL

- Electrolyte panel- includes anion gap (calculated), CO₂, chloride, potassium and sodium will be renamed to Electrolyte panel- includes CO₂, chloride, potassium and sodium
- Lipid panel profile includes cholesterol, HDL and Triglycerides will be renamed to Lipid panel profile- includes cholesterol, HDL, LDL, and Triglycerides
- Renal function panel- includes albumin, calcium, CO₂, chloride, creatinine, phosphate, potassium, sodium and BUN will be renamed to Renal function panel- includes albumin, glucose, calcium, CO₂, chloride, creatinine, phosphate, potassium, sodium and BUN
- Thyroxin (T₄), free, prenatal will be renamed Thyroxine (T₄), total
- Tri-iodothyronine (T₃), uptake, total, prenatal will be renamed Tri-iodothyronine (T₃), free