

**Department of State Health Services
Council Agenda Memo for State Health Services Council
November 28-29, 2012**

Agenda Item Title: Amendments to rules concerning fee schedules for clinical testing, newborn screening, and chemical analysis

Agenda Number: 5.a

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Laboratory Services Section (LSS), in the Division for Disease Control and Prevention Services, supports public health programs by providing analysis of human, animal, and environmental specimens and samples. About 1.5 million specimens and environmental samples are processed each year including: the screening of 400,000 newborns for 28 disorders; the testing of 450,000 specimens as part of the Texas Health Steps Program; the testing of 265,000 microbiological specimens associated with communicable diseases, foodborne outbreaks, tuberculosis, infectious agents, viruses, rabies, and other health threats; and the testing of 27,000 drinking water samples.

The Laboratory is supported with \$33.5 million in general revenue, which includes \$9.7 million in Public Health Service Fees and \$14.7 million in Medicaid reimbursements. An additional \$4.1 million in federal funding is received from the Centers for Disease Control and Prevention, Assistant Secretary for Preparedness and Response, Food and Drug Administration, and the Environmental Protection Agency. Program costs are offset by other fees for services and inter-agency contracts.

Summary:

The purpose of the amendments is to make slight adjustments in fee schedules for clinical testing, newborn screening, and chemical analysis. The proposed changes amend the recently adopted rules regarding all DSHS lab fees by adding some new tests, deleting low volume tests, and deleting clinical tests performed at the Women's Health Laboratory (WHL), which closed on August 31, 2012. A low volume test is defined as one that was ordered less than 100 times in 2011; that is not considered a core public health test; and is readily available from commercial laboratories.

Pap smears and cytology offered exclusively at the WHL in the rules would be eliminated. Other tests performed at WHL, such as routine clinical tests and tuberculosis testing would be performed at the remaining two DSHS laboratories—South Texas Laboratory and the Austin laboratory. Those few clinical tests that would no longer be offered by DSHS under this rulemaking proposal are available at commercial laboratories. The proposed fee changes reflect DSHS's current costs for providing the services at issue.

Key Health Measures:

The adjusted fee schedule more reflects the Laboratory's true costs of testing and complies with Senate Bill 80, 82nd Legislature, Regular Session, 2011, regarding the fee and revenue recovery methodology. Adjusting the fee schedule will ensure that the Laboratory is more likely to generate enough revenue to maintain the current level of services to all providers.

The Laboratory has two performance measures that are reported to the Texas Legislature: number of laboratory tests performed; and average cost per test performed. The proposed rule changes that would increase some fees may cause a decrease in the number of laboratory tests performed (i.e., current submitters not wanting to pay higher fees) which may affect the number of laboratory tests performed and reported to the Legislature.

Examples of Current Vs. Proposed Fee Cost Comparison¹

Test	CPT	Number in FY 2011	Current price	Calculated price	% Increase or Decrease
<i>Bordetella pertussis</i> , <i>Parapertussis</i> , and <i>Bordetella holmesii</i> detection by real-time polymerase chain reaction (PCR)	87798	751 ²	\$32.11	\$213.79	566% increase
Influenza surveillance without culture (typing, PCR)	87502	619 ³	\$248.00	\$131.32	53% decrease
Nucleic acid amplification for <i>Mycobacterium tuberculosis</i> (<i>M. tuberculosis</i>) complex	87556	0 ⁴	\$197.41	\$166.70	16% decrease
QuaniFERON (tuberculosis serology)	86480	8375	\$84.45	\$53.66	36% decrease

- 1- The four tests listed above are the only tests in this proposed rule package with fees that changed from current prices.
- 2- This increase in price is necessary because an error was found in the original cost calculation (as revised in the recently concluded rulemaking action pertaining to the entire LSS fee schedule) and needed to be corrected. The cost methodology used is as described in the Background and Purpose section of the Preamble.
- 3- The price of this test decreased because we propose to no longer perform culture as part of this test.
- 4- The NAA for MTB test is a proposed new test. (It is not the same NAA test that we performed in 2011). So we performed zero of this new NAA test in 2011. The number of the old NAA test performed in 2011 was 43. The specimen acceptance requirements for the old test were very restrictive which limited the number of specimens that could be tested. The proposed new NAA test has less restrictive specimen acceptance criteria therefore the laboratory anticipates many more requests for this new test.

Summary of Input from Stakeholder Groups:

DSHS notified stakeholders by letter on October 25, 2012, that DSHS is proposing changes to rules related to the laboratory's fee schedule adopted in October 2012. The letter explains amendments include fees for new tests; the deletion of some tests and their fees; and changes to some fees which may be higher or lower than the fee listed on the existing fee schedule. Many of the changes to existing rules are related to the closing of the WHL. Tests performed on clinical specimens at WHL are proposed to be deleted. Some tests that were performed at WHL will continue to be offered at the remaining two DSHS laboratories and will be included in the proposed amendments.

A complete list of the proposed changes to tests offered at the South Texas Laboratory and the Austin laboratory was attached to the letter and the submitters were reminded that there would be an official 30-day comment period once the proposed amendments are published in the *Texas Register*. The letter also included contact information that submitters may use to provide informal comments prior to the official comment period. To date no responses have been received.

The proposed rules will be posted on the LSS website. When posted, stakeholders will be notified that the proposed amended rule language is available for review.

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in agenda item #5.a.

**Approved by Assistant
Commissioner/Director:**

Lucina Suarez, Ph.D., Acting Assistant
Commissioner for Disease Control and
Prevention Services Division

Date: 11/2/2012**Presenter:** Dr. Susan Tanksley,
Director**Program:** Laboratory Operations Unit,
Laboratory Services Section**Phone No.:** 512-776-2468**Approved by CCEA:**

Carolyn Bivens

Date: 11/8/2012

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 73. Laboratories
Amendments §73.54, §73.55

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes amendments to §73.54 and §73.55 concerning fee schedules for clinical testing and newborn screening, and chemical analysis.

BACKGROUND AND PURPOSE

This rule package concerns fees for laboratory services; specifically, fee schedules for clinical testing, newborn screening and chemical analysis. The rule package reflects proposed changes to the version of the rules that was recently amended in a larger rulemaking action pertaining to all department lab fees. Since the close of the public comment period for that rulemaking action, circumstances have occurred that make it necessary to submit these proposed amendments. A low volume test is defined as one that was ordered less than 100 times in 2011; that is not considered a core public health test; and is readily available from commercial laboratories. In addition, §73.54 would be reorganized by removing the language currently at subsection (c), which relates to tests performed on clinical specimens at the department's Women's Health Laboratory (WHL), since that laboratory permanently closed on August 31, 2012. Some services offered exclusively at WHL in the rules, such as pap smears and cytology, would be eliminated through this new rulemaking proposal while some of the other tests (e.g. routine clinical tests and tuberculosis testing) would be performed at the remaining two department laboratories--South Texas Laboratory (STL) and the Austin laboratory. The WHL submitters have been notified as to which department laboratory will perform their testing as of September 1, 2012. Those few clinical tests which would no longer be offered by department under this rulemaking proposal are available at commercial laboratories. The proposed fee changes reflect the department's current costs for providing the services at issue (see full discussion in this preamble).

The proposed amendments comport with Texas Health and Safety Code, §§12.031, 12.032, and 12.0122 that allow the department to charge fees to a person who receives public health services from the department, and which is necessary for the department to recover costs for performing laboratory services.

Tests that will no longer be offered by the department are readily available elsewhere and only one specific fee would be increased by virtue of these rule changes. This increased fee is proposed to correct an error in the original cost calculation for this fee in the large rulemaking action recently completed (the only error identified out of the approximately 700 fees calculated using the new methodology in that rule package). This one fee would increase from \$32.11 to \$213.79. This fee is for a PCR test for *Bordetella pertussis*, *Parapertussis*, and *Bordetella holmesii*, which our records show has recently only been requested 800 - 1,000 times annually, which is a low number in the overall spectrum of laboratory services purchased from the department.

Senate Bill (SB) 80, 82nd Legislature, Regular Session, 2011, requires that the department: (1) develop, document and implement procedures for setting fees for laboratory services, including updating and implementing a documented cost allocation methodology that determines reasonable costs for the provision of laboratory tests; and (2) analyze the department's costs and update the fee schedule as needed in accordance with Texas Health and Safety Code, §12.032(c). In that recently-concluded rulemaking action, the LSS developed and documented a cost accounting methodology and determined the costs for each test performed. The methodology for developing cost per test included calculating the specific costs of performing the test or analysis and the administrative and overhead cost necessary to operate the state laboratories in question. It is these figures together which determined the revised fee amount for each of the tests in these fee schedules. In order to determine the specific cost for each test or analysis, LSS performed a work load unit study for every procedure or test offered by the laboratory. A work load unit was defined as a measurement of staff time, consumables and equipment required to perform each procedure from the time the sample enters the laboratory until the time the results are reported. More than 3,000 procedures performed by the department's laboratory were included in this analysis. These procedures translated to approximately 700 different tests listed the department fee schedule. In the current rulemaking proposal, this same approach was employed on a much smaller number of tests. These proposed fee changes reflect the department's current costs for providing the services at issue.

The proposed rule amendments would affect only those individuals, public health departments, state agencies, contractors, and medical providers that purchase the particular tests at issue in this rulemaking proposal. Stakeholders were notified of these proposed rule changes by letter in October 2012. Stakeholders include some health care providers, local health department laboratories, and professional associations such as the Texas Medical Association and the Texas Hospital Association. This letter was also posted on the LLS website.

SECTION-BY-SECTION SUMMARY

Existing §73.54(a)(1)(B)(i) and (iii) are proposed to be amended by deleting two low volume tests, Antibody identification and Antibody titer, respectively and by renumbering the remaining subsection in this section to account for the removal for these two tests. These tests are proposed for deletion to make more efficient use of laboratory staff and to lower costs.

Existing §73.54(a)(1)(C)(iii) is proposed to be amended by deleting clause (iii), Phenylketonuria (PKU) full gene sequencing. This test is proposed for deletion to make more efficient use of laboratory staff and to lower costs.

Existing §73.54(a)(2)(A)(vii)(IV) is proposed to be amended by updating the name of the test to *Bordetella pertussis*, *Parapertussis*, and *Bordetella holmesii* detection by real-time polymerase chain reaction (PCR) to more accurately identify the test; and by correcting the price. This increase in price is necessary because an error was found in the original cost calculation (as revised in the recently-concluded rulemaking action pertaining to the entire LSS fee schedule) and needed to be corrected. The fee for the test would increase from \$32.11 to \$213.79. The cost methodology used is as described in the Background and Purpose section in this preamble.

Existing §73.54(a)(2)(A)(vii) is proposed to be further amended by inserting a new subclause (VII) for tests performed for Gonorrhea/Chlamydia (GC/CT) and by renumbering the remaining subsection to improve readability and achieve consistency of format.

Existing §73.54(a)(2)(C)(i)(I)(-e-) is proposed to be amended by lowering the price to account for the implementation of a new technology which has lowered the cost of performing the test. The price for this test, Nucleic acid amplification for *Mycobacterium tuberculosis* (*M. tuberculosis*) complex would decrease from \$197.41 to \$166.70. Existing §73.54(a)(2)(E)(ii), (vii) and (xvi) are proposed to be amended by deleting the following low volume tests: (ii) *Aspergillus*; (vii) Fungus; and (xvi) Legionella. These tests are proposed for deletion to make more efficient use of laboratory staff and to lower costs.

The remaining subclauses have been renumbered to account for these changes.

New §73.54(a)(2)(E)(xii) is proposed to be amended by the addition of a new subclause (III) that is necessary for a new test for HIV Combo Ag/AB EIA for \$7.90. Existing §73.54(a)(2)(E)(xxi) renumbered as (xviii) is proposed to be amended by lowering the price for QuantiFeron (tuberculosis serology) from \$84.45 to \$53.66 to reflect the implementation of new technology which has lowered the cost of performing the test.

In §73.54(a)(2)(F)(ii)(IV), there is a new test for the West Nile virus for the amount of \$57.87.

Existing §73.54(a)(2)(F)(x) is proposed to be amended by reorganizing all tests related to influenza under a new subclause to improve readability and achieve consistency of format. Existing §73.54(a)(2)(F)(x) and (xi) are proposed to be renumbered as §73.54(a)(2)(F)(x)(I) and (II). New §73.54(a)(2)(F)(x)(III) is proposed to add a new test for Influenza pyrosequencing for antiviral resistance for the amount of \$13.11. Existing §73.54(a)(2)(F)(xii) is proposed to be renumbered as §73.54(a)(2)(F)(x)(IV). Existing §73.54(a)(2)(F)(xiii) is proposed to be renumbered as §73.54(a)(2)(F)(xi). New §73.54(a)(2)(F)(xii) and (xiii) are proposed to add a new test for Mumps, real-time PCR for the amount of \$127.83 and a new text for Respiratory viral panel for the amount of \$152.02.

New §73.54(b)(3) is a proposed new paragraph to add tests related to emergency preparedness Influenza A, PCR in the amount of \$125.00 and for Ricin, PCR--\$150.00. Existing §73.54(b)(3) - (7) are proposed to be renumbered as §73.54(b)(4) - (8). New §73.54(b)(6)(A)(iv) is proposed to add a new test for the Identification of AFB isolate, DNA probe in the amount of \$44.63. Existing §73.54(b)(6)(A)(iv) and (v) are proposed to be renumbered as §73.54(b)(6)(A)(v) and (vi) respectively.

Existing §73.54 is proposed to be reorganized by removing subsection (c), which relates to tests performed on clinical specimens at the department's Women's Health Laboratory (WHL), since that laboratory was permanently closed on August 31, 2012. Some services offered exclusively at WHL in the rules, such as pap smears and cytology, would be eliminated through this new rulemaking proposal while some of the other tests would be performed at the remaining two department laboratories, STL and the Austin laboratory (e.g. routine clinical tests and tuberculosis testing). Those clinical tests, which would no longer be offered by the department

under these proposed amendments, are readily available at commercial laboratories. Subsequent subsections are proposed to be renumbered accordingly.

New §73.54(c)(4)(A)(iv) is proposed to add a new test for *Cronobacter sakazakii* for the amount of \$66.07. New §73.54(c)(4)(A)(v)(II) is proposed to be amended by adding a new test for Non-0157 STEC in the amount of \$121.52 and by reorganizing all tests related *Escherichia coli* under a new clause to improve readability and achieve consistency of format. Existing §73.54(d)(4)(A)(iv) and (v) are proposed to be renumbered as §73.54(c)(4)(A)(v)(I) and III). Existing §73.54(d)(8)(A) is proposed to be amended by adding a new test for West Nile Virus (WNV), mosquitoes, PCR in the amount of \$57.87 in new §73.54(c)(8)(A)(v).

Existing §73.54(d)(9) is proposed to be reorganized by deleting existing §73.54(d)(9)(A), (B) and (F) which are low volume tests. These tests are proposed for deletion to make more efficient use of laboratory staff and to lower costs. Existing §73.54(d)(9)(C), (D) and (E) are proposed to be renumbered as §73.54(c)(9)(A), (B) and (C) respectively.

Existing §73.54(d) - (f) was renumbered as §73.54(c) - (e). Since renumbering the subsections, all existing text has to be shown even if no changes are included.

New §73.54(e)(4) is proposed to add a new specimen processing and storage service, with an associated fee of \$25.

Section 73.55(3)(A)(x) is proposed to add a new test for gluten in the amount of \$92.11 and existing §73.55(3)(A)(x) - (xx) are proposed to be renumbered as §73.55(3)(A)(xi) - (xxi) respectively. New §73.55(9)(G) is proposed to add a new composite sample storage service and associated fee of \$19.23.

FISCAL NOTE

Dr. Grace Kubin, Director, LSS, has determined that for each year of the first five year years the sections are in effect, there will be fiscal implications to the state as a result of administering the sections as proposed. It is impossible to predict the volume of testing the laboratory will receive under a revised fee schedule as well as the actual resulting revenues, but this rulemaking proposal reflects the fee calculation methodology derived and implemented in the large recently-completed rulemaking action which revised the entire department laboratory fee schedule, consistent with SB 80, 82nd Legislature, Regular Session, 2011. SB 80 requires the LSS to develop and document a cost accounting methodology to determine costs for each test performed. Because the proposed rulemaking would reduce fees for some tests, the volume of those same tests may increase and thus result in a net increase in revenue. Some fees are being lowered to reflect cost savings the department recently realized through changes in technology. The correction to the *Bordetella pertussis*, *Parapertussis*, and *Bordetella holmesii* fee would result in increased revenues to department unless the increase results in a substantial decrease of orders for that test.

General revenue from the state for the LSS operations has been reduced by \$7.9 million (roughly 10%) for fiscal years 2012 - 2013. A portion of the revenues which come to LSS will be used to

pay the bond debt on the laboratory building at the department's Central Office main campus, as required by the General Appropriations Act (GAA). Dr. Kubin has also determined that there may be an increased financial burden placed on certain department programs, as well as on local health departments, health care providers, and others that submit specimens for testing for the one test which would experience a fee increase in these proposed amendments. Some of the impacted external submitters may be small or micro-businesses. However, the fees for some tests would go down under the proposed rule amendments, and so the fiscal impact would be determined by the combination of tests ordered by the particular submitter.

MICRO-BUSINESS AND SMALL BUSINESSES IMPACT ANALYSIS

Varieties of entities, and some few persons, approach the department to purchase laboratory services. Many of those services are currently included in department rules with fee schedules which list amounts for each service. The proposed amendments in this rulemaking proposal include one fee which would be increased, *Bordetella pertussis*, *Parapertussis*, and *Bordetella holmesii* detection by real-time polymerase chain reaction (PCR). As discussed previously, that proposed increase is to correct a fee calculation error in the previous rulemaking action, recently concluded, which updated the entirety of the LSS fee schedule consistent with SB 80. The corrected fee amount, from \$32.11 to \$213.79, would properly reflect the methodology used in that previous rulemaking action, which was designed to recoup the departments costs related to providing the service in its laboratories. Some of these proposed amendments would decrease other fee amounts for specific tests. The one fee increase may not be offset by the other fee decreases, for a particular submitter, and thus may have an adverse economic impact on such a small or micro-business. Since this increased fee will potentially impact all submitters (ie., anyone who might order this test, alone or in combination with other tests), the department analysis under the Economic Impact Statement in this preamble will also serve to satisfy the Small Business Impact Analysis required by Texas Government Code, §2006.002(a).

Texas Government Code, Chapter 2006, was amended by the 80th Legislature, Regular Session, 2007, (House Bill (HB) 3430) to require that, before adopting a rule that may have an adverse economic effect on small businesses, a state agency must first prepare an Economic Impact Statement and a Regulatory Flexibility Analysis.

The definition of a "small business" for purposes of this requirement was codified at Texas Government Code, §2006.001(2). Under this definition, a "small business" is an entity that is: for profit, independently owned and operated; and have fewer than 100 employees or less than \$6 million in annual gross receipts. Independently owned and operated businesses are self-controlling entities that are not subsidiaries of other entities or otherwise subject to control by other entities (and are not publicly traded).

Dr. Kubin has determined that there may be an adverse economic effect on those small businesses who submit specimens or samples to the LSS for analysis using the one test which would experience a fee increase under the proposed amendments. Therefore, the following two analyses have been performed:

--ECONOMIC IMPACT STATEMENT

The Economic Impact Statement in this preamble does not explicitly cover “micro-businesses,” but Texas Government Code, §2006.002(a), requires an analysis of the impacts on such businesses. The department believes that some of the health care providers impacted by this proposed rule will be “micro-businesses” as well as “small businesses,” and thus the department’s analyses regarding the latter will also be applicable to the former. While it is true that a micro-business may be inherently somewhat less able to absorb new increased fees than a small business, the department believes that all businesses periodically experience increases in the cost of doing business. The revised fees in this package of proposed amendments were derived using the mandated methodology in SB 80. One fee went up (correcting a previous calculation error), and some fees went down. The impact on a particular submitter will vary depending on, among other things, what particular tests are ordered by that submitter.

The laboratory does not collect information on the size of a submitter’s business, and so it does not have direct data at hand to definitely determine what percentage of its usual submitters are small or micro-businesses. However, the department has made an estimate, using an approach suggested in the Texas Office of the Attorney General guidance document associated with HB 3430. A review of The North American Industry Classification System (NAICS) on the U.S. Census Bureau website revealed four classifications that appear to represent all the submitter types for the LSS. Specific information on the number of small businesses listed for each of these codes in 2007 was found on the Texas Comptroller of Public Accounts Website. The NAICS codes that represent submitters to the LSS include: "6221" - General Medical and Surgical Hospitals (364 businesses listed of which 56 are defined as small businesses), "6214"- Outpatient Care Centers (578 businesses listed of which 442 are defined as small businesses), and "6223" - Specialty (except Psychiatric and Substance Abuse) Hospitals (116 businesses listed of which 80 are defined as small businesses). The total number of businesses listed for these three classification codes is 1058. Of that number, only 576 of the businesses listed (physician, clinics, and hospitals are small businesses that could be affected by these rule amendments. This estimate corresponds to approximately 4% of the total number of submitters who submitted specimens to the LSS from January 1, 2010 through June 30, 2011, extrapolating based on the assumptions and data discussed previously. The department believes that most of these 578 small or micro-businesses are contractors for department programs such as Texas Health Steps and HIV Prevention. Therefore, the economic impact would be to the department program which hires each contractor, and it is those department programs which would ultimately have to absorb the fee increases. Subtracting these contractors from the total, the department believes this leaves a much smaller number of non-department contractor small and micro-businesses that could be impacted by any fee increases.

--REGULATORY FLEXIBILITY ANALYSIS

Texas Government Code, Chapter 2006, was amended by the 80th Legislature, Regular Session, (2009), (HB 3430) to require, as part of the rulemaking process, state agencies to prepare a Regulatory Flexibility Analysis that considers alternative methods of achieving the purpose of the rule. The department has considered several options for minimizing the adverse impacts on small businesses.

Option 1 - Maintain the *Bordetella pertussis*, “*Parapertussis*, and *Bordetella holmesii*” fee at its current level. The department cannot implement this option because SB 80 requires the department to develop, document and implement procedures for setting fees for laboratory services, including updating and implementing a documented cost allocation methodology that determines reasonable costs for specific types of tests, as well as analyzing the department’s costs and updating the fee schedule as needed in accordance with Texas Health and Safety Code, §12.032(c). The one fee correction included in these proposed amendments to the rule was derived using that methodology required by SB 80, consistent with Texas Health and Safety Code, §12.032. Keeping the fee at its current level would not reflect the use of the required methodology.

Option 2 - Allow an exemption from *Bordetella pertussis*, *Parapertussis*, and *Bordetella holmesii* fee increase for small and micro-businesses. Texas Health and Safety Code, §12.031, §12.032, and §12.0122 allow the department to charge fees to a "person" who receives public health services from the department, with the fee amount reflecting that which is necessary for the department to recover costs for performing laboratory services. Public health service fees generated by laboratory testing are appropriated to the LSS and are used to purchase supplies and equipment necessary for testing and to pay salaries of laboratory personnel (as well as to service the bond debt for the main department laboratory building in Austin). If the department were to allow an exemption from any fees for small and micro-businesses, the reduction in revenues generated would impact the department’s ability to maintain the current level of laboratory services. Such a fee structure would also not reflect the SB 80 methodology discussed at Option 1. Additionally, Texas Health and Safety Code, §12.032(e), states that the department may not fail to provide the service at issue if the submitter can demonstrate a financial inability to pay. So, if a small or micro-business could demonstrate, through submission of appropriate documentation that it truly was unable to pay for the one laboratory service at issue that would be an option for such a business. It should be noted, though, that an inability to pay is not the same thing as not having budgeted sufficient funds to pay, for example. The submitter would have to demonstrate, to the agency’s satisfaction (through submission of tax returns and other documentation), that it simply did not have the funds at all to pay for the service in question.

Option 3 - Change *Bordetella pertussis*, *Parapertussis*, and *Bordetella holmesii* fee to level which preceded the recent rulemaking revision to the overall LSS fee schedule. Texas Health and Safety Code, §12.031, §12.032, and §12.0122 allow the department to charge fees to a person who receives public health services from the department, and those fees cannot exceed the amount which is necessary for the department to recover costs for performing laboratory services. Public health service fees generated by laboratory testing are appropriated to the LSS and are used to purchase supplies and equipment necessary for testing and to pay salaries of laboratory personnel (as well as to service the bond debt for the main department’s laboratory building in Austin). If the department were to lower this fee back to its level prior to the recently-completed rulemaking action, as opposed to raising it as proposed in these amendments, the reduction in revenues generated would have a negative impact on the department’s ability to maintain the current level of laboratory services. Such a fee structure would also not reflect the SB 80 methodology discussed at Option 1.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed rules do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of a government action and, therefore, do not constitute a taking under Texas Government Code, §2007.043.

PUBLIC BENEFIT

In addition, Dr. Kubin has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections will be the continued operation of the department's laboratories, which perform important public health activities every day. The public would also benefit by the department adjusting its fees to recover the costs associated with providing these laboratory services, which is money for LSS operations that would then reduce the amount of funding required to come from the public's tax dollars (i.e. General Revenue). The public would also benefit from the proposed changes designed to improve clarity, readability and user-friendliness of the rules, in that there is a public benefit whenever a state improves the efficiency of its operations. The public will also benefit from the list of laboratory services currently available being updated for accuracy.

PUBLIC COMMENT

Comments on the proposal may be directed to Norma Vela, Laboratory Services Section, Mail Code 1947, P.O. Box 149307, Austin, TX 78714-9347, (512) 771-6626 or by email at norma.vela@dshs.state.tx.us. Comments will be accepted for 30 days following the date of publication of this proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' legal authority to adopt.

STATUTORY AUTHORITY

The amendments are authorized under Texas Health and Safety Code, §12.031 and §12.032 which allow the department to charge fees to a person who receives public health services from the department, §12.034 which requires the department to establish collection procedures, §12.035 which required the department to deposit all money collected for fees and charges under §12.032 and §12.033 in the state treasury to the credit of the department's public health service fee fund, and §12.0122 which allows the department to enter into a contract for laboratory services; and Texas Code, §531.0055. and Texas Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Texas Health and Safety Code, Chapter 1001.

The amendments affect the Texas Health and Safety Code, Chapters 12 and 1001; and Texas Government Code, Chapter 531.

Legend: (Proposed Amendments)

Single Underline = Proposed new language

[Bold Print and Brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

§73.54. Fee Schedule for Clinical Testing and Newborn Screening.

(a) Tests performed on clinical specimens, Austin Laboratory.

(1) Biochemistry and genetics.

(A) (No change.)

(B) Clinical chemistry.

[(i) Antibody identification--\$260.70.]

(i) **[(ii)]** Antibody screen--\$20.51.

[(iii) Antibody titer--\$46.07.]

(ii) **[(iv)]** Blood typing ABO--\$20.51.

(iii) **[(v)]** Cholesterol--\$4.07.

(iv) **[(vi)]** Glucose:

(I) glucose fasting--\$3.96;

(II) glucose post prandial (1 hour)--\$3.96;

(III) glucose post prandial (2 hour)--\$7.91;

(IV) glucose random--\$3.96;

(V) glucose tolerance test 1 hour--\$7.91;

(VI) glucose tolerance test 2 hour--\$11.87; and

(VII) glucose tolerance test 3 hour--\$15.82.

(v) **[(vii)]** Hematocrit--\$6.62.

(vi) **[(viii)]** Hemoglobin--\$1.53.

(vii) [~~(ix)~~] Hemoglobin electrophoresis--\$3.98.

(viii) [~~(x)~~] High-density lipoprotein (HDL)--\$7.14.

(ix) [~~(xi)~~] Lead--\$3.47.

(x) [~~(xii)~~] Lipid panel (consists of cholesterol, triglycerides, high density lipoprotein (HDL), and low density lipoprotein (LDL))--\$10.57.

(xi) [~~(xiii)~~] Red blood cell antigens, other than ABO or Rh(D)--\$260.70.

(xii) [~~(xiv)~~] RH typing--\$20.51.

(C) DNA Analysis.

(i) - (ii) (No change.)

[(iii) Phenylketonuria (PKU) full gene sequencing--\$1726.03.]

(iii) [~~(iv)~~] Galactosemia common mutation panel--\$383.21.

(iv) [~~(v)~~] Medium chain acyl-CoA dehydrogenase deficiency (MCAD), common mutation panel--\$280.79.

(v) [~~(vi)~~] Very long chain acyl-CoA dehydrogenase deficiency (VLCAD), full gene sequencing--\$1596.93.

(2) Microbiology.

(A) Bacteriology. Charges for bacteriology testing will be based upon the actual testing performed as determined by suspect organisms, specimen type and clinical history provided.

(i) - (vi) (No change.)

(vii) Definitive identification:

(I) - (III) (No change.)

(IV) *Bordetella pertussis*, *Parapertussis*, and *Bordetella holmesii* detection by real-time polymerase chain reaction (PCR)--\$213.79 [32.11];

(V) - (VI) (No change.)

(VII) *Gonorrhea/Chlamydia* (GC/CT):

- probe--\$37.66; and
- (-a-) GC/CT, amplified RNA probe--\$20.28;
- (-b-) GC culture confirmation by amplified or direct
- (-c-) GC screen--\$44.54.
- (VIII) [(VII)] gram negative rod--\$261.00;
- (VIX) [(VIII)] gram positive rod--\$226.12;
- (X) [(IX)] *Haemophilus*--\$242.23;
- (XI) [(X)] *Legionella*--\$265.57;
- (XII) [(XI)] *Neisseria meningitidis*--\$390.52;
- (XIII) [(XII)] pertussis--\$287.98;
- (XIV) [(XIII)] *Staphylococcus*--\$188.88; and
- (XV) [(XIV)] *Streptococcus*--\$258.91.
- (viii) - (xv) (No change.)
- (B) (No change.)
- (C) Mycobacteriology/mycology.
- (i) Acid fast bacilli (AFB).
- (I) Clinical specimen, AFB isolation and identification.
- (-a-) - (-d-) (No change.)
- (-e-) Nucleic acid amplification for *Mycobacterium tuberculosis* (*M. tuberculosis*) complex--\$166.70 [**197.41**].
- (-f-) - (-g-) (No change.)
- (II) (No change.)
- (ii) - (v) (No change.)
- (D) (No change.)

(E) Serology.

(i) (No change.)

[(ii) *Aspergillus*--\$84.13.]

(ii) **[(iii)] *Brucella*--\$74.52.**

(iii) **[(iv)] Cat scratch fever (*Bartonella*)--\$171.30.**

(iv) **[(v)] Cytomegalovirus (CMV):**

(I) IgG--\$399.97; and

(II) IgM--\$161.02.

(v) **[(vi)] *Ehrlichia* indirect fluorescent antibody (IFA)--\$174.20.**

[(vii) Fungus:]

[(I) fungal identification (blastomycosis, coccidioidomycosis, histoplasmosis)--\$142.05; and]

[(II) fungal panel (blastomycosis, coccidioidomycosis, histoplasmosis)--\$130.55.]

(vi) **[(viii)] Hantavirus IgG/IgM--\$362.05.**

(vii) **[(ix)] Hepatitis A:**

(I) IgM--\$317.74; and

(II) total--\$219.60.

(viii) **[(x)] Hepatitis B:**

(I) core antibody--\$143.90;

(II) core IgM antibody--\$295.64;

(III) surface antibody (Ab)--\$103.84; and

(IV) surface antigen (Ag)--\$51.45.

(ix) **[(xi)] Hepatitis BeAb--\$109.20.**

(x) [(**xii**)] Hepatitis BeAg--\$195.14.

(xi) [(**xiii**)] Hepatitis C (HCV)--\$25.68.

(xii) [(**xiv**)] Human immunodeficiency virus (HIV):

(I) HIV 1, 2, plus 0 screen--\$11.40;

(II) serum, multi spot--\$40.74; and [.]

(III) HIV Combo Ag/Ab EIA--\$7.90.

(xiii) [(**xv**)] Human immunodeficiency virus-1 (HIV-1):

(I) enzyme immunoassay (EIA) Dried Blood Spots (DBS)--

\$14.32;

(II) enzyme immunoassay (EIA) oral fluid--\$69.99;

(III) Nucleic acid amplification test (NAAT)--\$7.79;

(IV) western blot serum--\$277.23;

(V) western blot DBS--\$277.23; and

(VI) western blot oral--\$324.71.

[(**xvi**) *Legionella*--\$168.42.]

(xiv) [(**xvii**)] Lyme (*Borrelia*) IgG/IgM Panel--\$706.25.

(xv) [(**xviii**)] Measles, mumps, rubella – *Varicella zoster* virus (MMR-VCV) Magnetic Immunoassay (MIA)--\$345.63.

(xvi) [(**xix**)] Mumps:

(I) epidemic parotitis IgG--\$154.46; and

(II) epidemic parotitis IgM--\$251.96.

(xvii) [(**xx**)] Q-Fever--\$234.97.

(xviii) [(**xxi**)] QuantiFERON (tuberculosis serology)--\$53.66
[\$84.45].

(xix) [(xxii)] *Rickettsia* panel (includes: Rocky Mountain spotted fever and typhus)--\$134.14.

(xx) [(xxiii)] Rubella:

(I) IgM--\$329.37; and

(II) screen--\$24.13.

(xxi) [(xxiv)] Rubeola:

(I) IgM--\$210.24; and

(II) Screen (IgG)--\$165.16.

(xxii) [(xxv)] Schistosoma enzyme immunoassay (EIA)--\$134.49.

(xxiii) [(xxvi)] Strongyloide enzyme immunoassay (EIA)--\$73.45.

(xxiv) [(xxvii)] Syphilis:

(FTA-ABS)--\$80.20;

(I) Confirmation fluorescent treponemal antibody absorbed

and

(II) Confirmation particle agglutination (TP-PA)--\$27.02;

(III) Rapid plasma reagin (RPR):

(-a-) screen (qualitative)--\$2.89; and

(-b-) titer (quantitative)--\$12.88.

(xxv) [(xxviii)] Toxoplasmosis--\$357.49.

(xxvi) [(xxix)] Tularemia (*Francisella tularensis*)--\$54.53.

(xxvii) [(xxx)] *Varicella zoster* virus (VCV)--\$345.63.

(xxviii) [(xxxi)] *Yersinia pestis* (Plague), serum--\$237.18.

(F) Virology.

(i) (No change.)

(ii) Arbovirus identification, PCR:

(I) (No change.)

(II) St. Louis Encephalitis (SLE)--\$60.18; **[and]**

(III) Western Equine Encephalitis(WEE)--\$60.41; and [.]

(IV) West Nile virus--\$57.87.

(iii) - (ix) (No change.)

(x) Influenza.

(I) [(x)] Influenza A/B identification, DFA--\$54.02.

culture]--\$248.00.

(II) [(xi)] Influenza Surveillance with culture [**Influenza,**

\$13.11.

(III) Influenza pyrosequencing for antiviral resistance--

PCR)--\$131.32 [**\$248.00**].

(IV) [(xii)] Influenza surveillance without culture (typing,

(xi) [(xiii)] Norovirus (Norwalk-like virus) PCR--\$55.77.

(xii) Mumps, real-time PCR--\$127.83.

(xiii) Respiratory viral panel--\$152.02.

(xiv) - (xix) (No change.)

(b) Tests performed on clinical specimens, South Texas Laboratory. Specimens that must be sent to a reference lab for testing will be billed at the reference laboratory price plus a \$3.00 handling fee.

(1) - (2) (No change.)

(3) Emergency Preparedness.

(A) Influenza A, PCR--\$125.

(B) Ricin, PCR--\$150.00.

(4) [(3)] Hematology.

- (A) CBC (complete blood count) with smear review--\$9.11.
- (B) CBC complete, automated with differential--\$1.51.
- (C) Differential, manual--\$9.89.
- (D) Hematocrit--\$6.01.
- (E) Hemoglobin, total--\$6.01.
- (F) Sedimentation rate--\$11.38.

(5) [(4)] Immunology.

- (A) Pregnancy test:
 - (i) serum--\$4.40; and
 - (ii) urine--\$4.24.
- (B) Rheumatoid factor--\$4.73.

(6) [(5)] Microbiology.

- (A) Mycobacteriology, Acid fast bacillus (AFB).
 - (i) Concentration--\$4.31.
 - (ii) Culture, any source--\$49.89.
 - (iii) Drug susceptibility studies:
 - (I) conventional susceptibility (each drug)--\$36.45; and
 - (II) MGIT susceptibility (each drug)--\$92.69.
 - (iv) Identification of AFB isolate, DNA probe--\$44.63.
 - (v) [(iv)] Identification, referred isolates, DNA probe--\$44.63.
 - (vi) [(v)] Smear only--\$5.09.
- (B) Parasitology, ova and parasites (concentration and trichrome stain)--\$67.17.
- (C) Serology, syphilis.

(i) Rapid plasma reagin (RPR):

(I) screen (qualitative)--\$7.99; and

(II) titer (quantitative)--\$7.99.

(ii) Confirmation particle agglutination (TP-PA)--\$9.30.

(D) Wet mount, vaginal--\$9.14.

(7) [(6)] Special chemistry.

(A) Ferritin--\$22.31.

(B) Follicle stimulating hormone (FSH)--\$15.10.

(C) Leuteinizing hormone (LH)--\$17.83.

(D) Prolactin--\$18.07.

(E) Prostate specific antigen (PSA), total--\$27.90.

(F) Thyroxin (T4), free, prenatal--\$35.53.

(G) Thyroid stimulating hormone (TSH), prenatal--\$9.41.

(H) Tri-iodothyronine (T3) uptake, total, prenatal--\$19.10.

(8) [(7)] Urinalysis.

(A) Creatinine clearance test--\$12.00.

(B) Protein, total, 24 hour--\$5.82.

(C) Microscopy with urinalysis (UA)--\$32.25.

(D) Urinalysis, no reflex--\$5.24.

(E) Urine microalbumin, random--\$5.69.

[(c) Tests performed on clinical specimens, Women's Health Laboratory.]

[(1) Bacteriology.]

[(A) Bacterial culture, routine:]

[(i) body fluid--\$33.19;]

[(ii) eye, ear, and nasopharynx (np)--\$36.67;]

[(iii) sputum/trach (tracheostomy)--\$35.35;]

[(iv) stool--\$37.35;]

[(v) throat--\$26.57;]

[(vi) urine--\$11.03;]

[(vii) urogenital--\$40.14; and]

[(viii) wound--\$92.82.]

[(B) Fecal occult blood--\$32.65.]

[(C) Fungus.]

[(i) clinical, definitive identification:]

[(I) mold, nocardia--\$87.80; and]

[(II) yeast identification--\$49.28.]

[(ii) reference culture:]

[(I) genital/urine--\$49.46;]

[(II) routine with KOH--\$29.44;]

[(III) skin, hair, nail--\$71.85; and]

[(IV) tissue with KOH--\$86.85.]

[(D) Genetic probe.]

[(i) Group B streptococcus--\$18.97.]

[(ii) Gonorrhea/Chlamydia (GC/CT):]

[(I) amplified GenProbe--\$19.72; and]

[(II) CT and GC, DNA--\$19.72.]

[(E) Gram stain smear with fecal WBC:]

[(i) fecal leukocytes--\$6.97; and]

[(ii) gram stain--\$11.20.]

[(F) KOH prep--\$6.88.]

[(G) Wet mount, vaginal--\$18.05.]

[(2) Cytology.]

[(A) Pap smear:]

[(i) conventional--\$13.28;]

[(ii) liquid based--\$25.45; and]

[(iii) physician interpretation--\$5.82.]

[(B) Non-gynecological (non-GYN) cytology--\$66.78.]

[(3) Clinical chemistry.]

[(A) Albumin, serum, urine or other source--\$1.27.]

[(B) Alkaline phosphatase--\$1.37.]

[(C) Alanine aminotransferase (ALT)--\$6.50.]

[(D) Amylase, serum--\$7.37.]

[(E) AST--\$1.32.]

[(F) Beta-human chorionic gonadotropin (beta-HCG) pregnancy test:]

[(i) qualitative--\$9.15; and]

[(ii) quantative--\$27.18.]

[(G) Blood typing:]

[(i) indirect COOMBS (AB screen)--\$26.31; and]

[(ii) ABO RH--\$15.36.]

[(H) BUN--\$1.48.]

[(I) CO2--\$1.35.]

[(J) Chloride, serum--\$1.35.]

[(K) Cholesterol, total--\$1.36.]

[(L) Cord blood panel – includes antihuman globulin tests (COOMBS); direct, each antiserum, blood typing ABO and RH (D)--\$10.83.]

[(M) Creatine Kinase--\$2.79]

[(N) Creatinine:]

[(i) 24 hour urine--\$16.37; and]

[(ii) 24 hour urine creatinine clearance--\$27.66.]

[(O) Electrolyte panel--includes anion GAP (calculated) CO2, chloride, potassium, sodium--\$2.83.]

[(P) Glucose:]

[(i) one half hour--\$5.96;]

[(ii) one hour--\$6.00;]

[(iii) 2 specimens--\$9.27;]

[(iv) 3 specimens--\$12.54;]

[(v) 4 specimens--\$15.84;]

[(vi) fasting--\$5.98;]

[(vii) gestational, 2 specimens--\$9.27;]

[(viii) postprandial, 0 and 2 hours--\$1.34; and]

[(ix) random--\$5.96.]

[(Q) Hematology.]

[(i) CBC automated, with differential--\$1.51.]

[(ii) CBC automated, without differential:]

[(I) CBC--\$12.13;]

[(II) eosinophil screen--\$6.63; and]

[(III) hematocrit--\$6.01.]

[(iii) CBC with manual differential--\$9.99.]

[(iv) Hemoglobin and hematocrit--\$6.78.]

[(v) Hemoglobin, total--\$6.01.]

[(R) Hepatic function panel--includes ALT, albumin, alkaline phosphatase, AST, bilirubin (direct and total), and protein (total)--\$2.47.]

[(S) High risk panel--includes cholesterol, glucose, and triglycerides--\$9.19.]

[(T) Lipid profile panel--includes cholesterol, HDL and triglycerides--\$8.84.]

[(U) Liver function panels:]

[(i) liver function test (LFT) 4--includes ALT, alkaline phosphatase, AST and bilirubin (total)--\$15.43; and]

[(ii) LFT 6--includes ALT, alkaline phosphatase, AST, bilirubin(total), creatinine, and BUN--\$12.71.]

[(V) LDH, total--\$19.95.]

[(W) Metabolic panels:]

[(i) basic panel--includes calcium, CO2, chloride, creatinine, glucose, potassium, sodium and BUN--\$3.65; and]

[(ii) comprehensive panel--includes ALT, albumin, alkaline phosphatase, AST, bilirubin (total), calcium, CO2, chloride, creatinine, glucose, potassium, protein (total), sodium, and BUN--\$5.38.]

[(X) Obstetric (OB) panels:]

[(i) OB--includes ABO RH, antibody screen, RBC, hepatitis B surface Ag, RPR, and rubella antibody--\$80.18; and]

[(ii) OB with CBC--includes ABO HR, antibody screen RBC, CBC with differential, hepatitis B surface Ag, RPR and rubella antibody--\$91.58.]

[(Y) Phosphorus--\$11.56.]

[(Z) Potassium, urine--\$15.49.]

[(AA) Protein:]

[(i) total--\$1.41; and]

[(ii) total, 24 hour urine--\$13.34.]

[(BB) Sodium--\$1.35.]

[(CC) Triglycerides--\$1.36.]

[(DD) Uric acid--\$4.07.]

[(EE) Urinalysis:]

[(i) with microscopic examination--\$32.25;]

[(ii) with microscopic examination and reflex culture--\$20.74;]

[(iii) bilirubin icotest confirmation--\$3.74;]

[(iv) chemstrip UGK--\$2.37;]

[(v) protein SSA confirmation--\$2.49; and]

[(vi) urine analysis without microscopic examination--\$17.00.]

[(4) Mycobacteriology.]

[(A)Acid fast bacillus (AFB).]

[(i) Anaerobic or aerobic identification--\$30.77.]

[(ii) Culture, Accuprobe--\$62.46.]

[(iii) Culture and smear, any source--\$59.14.]

\$47.58.]

[(iv) Drug susceptibility studies direct and indirect, each drug--

[(v) Smear only--\$5.09.]

[(B) Broth dilutions, minimum inhibitory concentration (MIC):]

[(i) BACTEC--\$140.91; and]

[(ii) MGIT--\$98.20.]

[(C) Rifabutin, agar susceptibility--\$47.57.]

[(5) Serology.]

[(A) Hepatitis B surface antigen (Ag)--\$14.68.]

[(B) Human papillomavirus (HPV)--\$68.68.]

[(C) Human immunodeficiency virus-1 (HIV-1):]

[(i) enzyme immunoassay (EIA) DBS--\$16.07; and]

[(ii) enzyme immunoassay (EIA) oral fluid--\$16.07.]

[(D) Rubella, IgG--\$16.37.]

[(E) Syphilis.]

[(i) Rapid plasma reagin (RPR):]

[(I) screen (qualitative)--\$7.99; and]

[(II) titer (quantitative)--\$7.99.]

[(ii) Confirmation particle agglutination (TP-PA)--\$9.30.]

[(6) Surgical pathology:]

[(A) level I--\$19.52;]

[(B) level II--\$45.91;]

[(C) level III--\$45.24;]

[(D) level IV--\$37.29; and]

[(E) level V--\$89.29.]

(c) [(d)] Non-clinical testing, Austin Laboratory.

(1) *Legionella*, culture--\$265.48.

(2) Bat identification--\$3.52.

(3) Entomology:

(A) insect identification--\$20.86;

(B) mosquito identification for surveillance--\$17.66; and

(C) mosquito larvae identification--\$6.04.

(4) Food.

(A) Bacterial identification.

(i) Bacillus:

(I) identification--\$101.16; and

(II) enumeration, most probable number (MPN)--\$245.53.

(ii) *Campylobacter* identification--\$145.40.

(iii) *Clostridium perfringens* identification--\$217.06.

(iv) *Cronobacter sakazakii*--\$66.07.

(v) *Escherichia coli*.

(I) [(iv)] *E.coli* 0157 identification--\$121.52.

(II) Non-0157 STEC--\$121.52.

(III) [(v)] *E.coli* enumeration (MPN)--\$180.97.

(vi) *Listeria* identification--\$150.75.

(vii) *Salmonella* identification--\$66.07.

(viii) *Shigella* identification--\$119.40.

- (ix) *Staphylococcus* identification--\$127.28.
- (x) *Yersinia* identification--\$62.48.
- (B) *Staphylococcus* enterotoxin detection--\$90.80.
- (C) Yeast and mold enumeration (MPN)--\$128.50.
- (D) Standard plate count--\$67.38.
- (5) Milk and dairy.
 - (A) Aflatoxin--\$65.63.
 - (B) Bacterial counts:
 - (i) coliform count, milk--\$33.97;
 - (ii) coliform count, containers--\$41.28;
 - (iii) standard plate count, milk--\$22.14; and
 - (iv) standard plate count, container--\$44.33.
 - (C) Dairy water--\$16.19.
 - (D) Freezing point--\$26.59.
 - (E) Growth inhibitors.
 - (i) Charm SL-6 beta-lactam test--\$81.14.
 - (ii) Charm SLBL beta-lactam test--\$58.91.
 - (iii) Charm II sulfonamide test--\$51.69.
 - (iv) Charm II tetracycline test--\$55.15.
 - (v) Delvo test--\$25.60.
 - (F) Phosphatase--\$37.82.
 - (G) Somatic cell counts.
 - (i) Direct microscope somatic cell count (DMSC):

(I) bovine (cow)--\$50.83; and

(II) caprine (goat)--\$58.54.

(ii) Optical somatic cell count (OSCC):

(I) bovine (cow)--\$51.05; and

(II) caprine (goat)--\$51.05.

(6) *Yersinia pestis* (plague), Nobuto--\$8.57.

(7) Shellfish.

(A) Bay water--\$25.76.

(B) Brevetoxin identification--\$242.95.

(C) *E.coli*, identification and enumeration (MPN)--\$151.43.

(D) Standard plate count--\$67.38.

(E) *Vibrio* identification--\$211.47.

(F) *Vibrio* identification and enumeration (MPN)--\$478.70.

(8) Virology.

(A) Arbovirus:

(i) culture from mosquito--\$44.25;

(ii) Eastern Equine Encephalitis (EEE), mosquitoes, PCR--\$60.39;

(iii) St. Louis Encephalitis (SLE), mosquitoes, PCR--\$60.18; **[and]**

(iv) Western Equine Encephalitis (WEE), mosquitoes, PCR--
\$60.41; and [.]

(v) West Nile Virus (WNV), mosquitoes, PCR--\$57.87.

(B) Rabies:

(i) detection, DFA--\$72.99;

(ii) detection, DFA, cell culture--\$158.77;

(iii) molecular typing--\$181.05; and

(iv) monoclonal typing--\$31.19.

(9) Water.

[(A) Bottled water--\$71.74.]

[(B) Fecal coliforms, multiple tube fermentation (MTF)--\$182.01.]

(A) ~~[(C)]~~ Heterotrophic plate count (HPC) bacteria in water (Simplate)--
\$84.86.

(B) ~~[(D)]~~ Potable water--\$16.19.

(C) ~~[(E)]~~ Surface water, (MPN) (Quanti-tray)--\$257.66.

[(F) Reagent water suitability--\$60.26.]

(d) ~~[(e)]~~ Non-clinical testing, South Texas Laboratory, Water bacteriology, potable water--
\$8.82.

(e) ~~[(f)]~~ Service charges.

(1) Restocking fee for NBS specimen collection kit--\$50.00.

(2) Thermometer calibration--\$12.23.

(3) Shipping and handling fees:

(A) AFB--\$50.20;

(B) Arbovirus reference sample--\$96.66; and

(C) CDC reference virus isolation--\$23.00.

(4) Specimen processing and storage--\$25.00.

§73.55. Fee Schedule for Chemical Analyses.

Fees for chemical analyses and physical testing.

(1) - (2) (No change.)

(3) The following fees apply to the analysis of food and food products.

(A) Inorganic analyses:

(i) - (ix) (No change.)

(x) gluten--\$92.11;

(xi) [(x)] insect identification, Food and Drug Administration (FDA) Technical Bulletin #2 [Number 2]--\$88.92;

(xii) [(xi)] meat protein, AOAC calculation--\$5.34;

(xiii) [(xii)] moisture (total water), USDA M01 method--\$63.00;

(xiv) [(xiii)] pH of food products, USDA PHM--\$43.12;

(xv) [(xiv)] phosphate determination-(tri-poly-phosphate), USDA PHS1--\$65.36;

(xvi) [(xv)] protein, total, USDA PRO1--\$81.14;

(xvii) [(xvi)] salt, USDA SLT--\$85.81;

(xviii) [(xvii)] soy protein concentrate, USDA SOY1 method--\$53.21;

(xix) [(xviii)] soya, USDA SOY1 method--\$53.21;

(xx) [(xix)] sulfite AOAC 980.17--\$28.27; and

(xxi) [(xx)] water activity, AOAC method 978.18--\$33.22.

(B) (No change.)

(4) - (8) (No change.)

(9) Additional charges.

(A) - (F) (No change.)

(G) Composite storage fee--\$19.23.