

**Department of State Health Services  
Council Agenda Memo for State Health Services Council  
April 3, 2013**

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

**Agenda Number:** 6.c.

**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 1.4 million specimens and environmental samples are processed each year, including:

- the testing of 310,000 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;
- the testing of 27,000 drinking water samples;
- the testing of 50,000 samples at the South Texas Laboratory; and
- 738,000 samples for the screening of 400,000 newborns for 28 disorders.

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 adjustments in fee schedules for clinical testing, newborn screening, and chemical analysis. The proposed changes add new tests, delete low volume tests, update fees, and delete clinical tests performed at the Women's Health Laboratory (WHL), which closed on August 31, 2012.

On November 29, 2012, the State Health Services Council approved rules concerning this topic. After the Council approved the rules packet, several new testing methodologies were approved for implementation in the DSHS Laboratory. These new testing methodologies would impact current fees in the fee schedule, so the revisions that were approved at the November Council meeting were withdrawn. The rules packet now includes these new tests and testing methodologies and the rule changes previously approved by the Council.

The rule changes increase two fees, due to a cost calculation error and a clerical error. The proposed rules also delete low volume tests, defined as ordered less than 100 times in 2011, not considered a core public health test, and readily available from commercial laboratories. Pap smears and cytology offered exclusively at the WHL are 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 reflects the Laboratory's true costs of testing and complies with Senate Bill 80, 82<sup>nd</sup> 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 reports two performance measures to the Texas Legislature that includes the number of laboratory tests performed and the average cost per test performed. The amendments include adding 57 new tests, deleting 12 low-volume tests, reducing the fee of 23 tests, changing the name and increasing the price of 1 test, changing the name and reducing the fee of 4 tests, increasing the price for 1 test, and changing the name of 8 tests for better clarity. Below is a representation of some of the price changes.

| Test   | Current Price | Proposed Price | % Increase or Decrease |
|--|---------------|----------------|------------------------|
| Pertussis , polymerase chain reaction will be renamed to <i>Bordetella pertussis</i> , <i>Parapertussis</i> , and <i>Bordetella holmesii</i> polymerase chain reaction (PCR) | \$32.11       | \$213.79       | 566% increase          |
| Single metal, ICP, EPA method 200.7 and EPA SW-846 method 6010C  | \$67.79       | \$114.04       | 68% increase           |
| Aerobic Isolation from clinical Specimen   | \$367.37      | \$303.92       | 17% decrease           |
| Anaerobic isolation from clinical specimen   | \$197.10      | \$118.39       | 40% decrease           |
| Neisseria  | \$390.52      | \$141.84       | 64% decrease           |
| Nucleic Acid Amplification for Mycobacterium Tuberculosis( M. Tuberculosis)  | \$197.41      | \$166.70       | 16% decrease           |
| QuantiFERON (tuberculosis serology)  | \$84.45       | \$53.66        | 36% decrease           |
| Rubella: screen  | \$24.13       | \$22.33        | 7% decrease            |
| Rubeola: screen (IgG)  | \$165.16      | \$21.35        | 87% decrease           |
| Toxoplasmosis  | \$357.49      | \$23.23        | 94% decrease           |
| Varicella zoster Virus, (VZV)  | \$345.63      | \$19.70        | 94% decrease           |
| Mercury, EPA method 245.1 and EPA SW-846 methods 7470A and 7471B   | \$192.35      | \$37.90        | 80% decrease           |
| South Texas Laboratory   |               |                |                        |
| Conventional susceptibility (each drug)  | \$36.45       | \$14.06        | 61% decrease           |
| MGIT susceptibility (each drug)  | \$92.69       | \$43.47        | 53% decrease           |

**Summary of Input from Stakeholder Groups:**

The LSS solicited preliminary feedback via email during the development of the proposed changes to these rules from the following stakeholders: Texas Medical Association, Texas Pediatric Association, Texas Hospital Association and Texas Association of Local Health Officials. Feedback provided by the stakeholders did not include substantive changes to these proposed rules. Once the rules are approved to be published in the *Texas Register*, a link to the publication will be posted on the DSHS LSS website.

**Proposed Motion:**

Motion to recommend HHSC approval for publication of rules contained in agenda item #6.c.

|   |                |                 |                                       |
|---|----------------|-----------------|---------------------------------------|
| <b>Approved by Assistant Commissioner/Director:</b> | Janna Zumbrun  | <b>Date:</b>    | 2/04/2013                             |
| <b>Presenter:</b>                                   | Grace Kubin    | <b>Program:</b> | Director, Laboratory Services Section |
| <b>Approved by CCEA:</b>                            | Carolyn Bivens | <b>Date:</b>    | 2/04/2013                             |

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 analyses. 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. These amendments would remove low volume tests and those performed at Women's Health Laboratory (WHL), would add new tests and rename the tests to more accurately reflect the actual procedure, and also would adjust test pricing, as described herein. A "low volume test," for purposes of this preamble, is one: that was ordered less than 100 times in 2011; that is not considered a core public health test by the department; and that 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 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 the 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 two specific fees would be increased by virtue of these rule changes. The increased fees are proposed to correct an error in the original cost calculation for one fee and correct a clerical error (cost methodology calculation conducted properly, but transcribed incorrectly into the rules itself) for another fee in the large rulemaking action recently completed (the only errors identified to date out of the approximately 700 fees calculated using the new methodology in that

rule package). 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. The second fee would increase from \$67.49 to \$114.04. This fee is for single metal, ICP, EPA method 200.7 and EPA SW-846 method 6010C for non-potable water, which our records show that during Fiscal Year 2011, the department only performed 93 times.

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 (adopted October, 2012), 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 testing reagents 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 in 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.

#### SECTION-BY-SECTION SUMMARY

Existing §73.54(a)(1)(A)(ii) is proposed to be amended by adding a new test Amino Acid Dietary Monitoring priced at \$16.61, with proposed renumbering accordingly.

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 of these two tests. These low-volume tests are proposed for deletion to make more efficient use of laboratory staff and to lower operational costs.

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

Existing §73.54(a)(2)(A)(i) is proposed to be amended by updating the name of the test to "Aerobic isolation from clinical specimen" to more accurately identify the test and by updating

the fee from \$367.67 to \$303.92. The reduced fee is the cost of isolation only; identification is covered in the existing fee schedule under the definitive identification section.

Existing §73.54(a)(2)(A)(iii) is proposed to be amended by updating the name of the test to “Anaerobic isolation from clinical specimen” to more accurately identify the test and by updating the fee from \$197.10 to \$118.39. The reduced fee is the cost of isolation only; identification is covered in the existing fee schedule under the definitive identification section.

Existing §73.54(a)(2)(A)(v) is proposed to be amended by deleting clause (v) “Cholera, culture confirmation--\$32.73.” This is not an accurate description of the test that is currently performed. The more accurate name and placement of the test will be in the definitive identification section.

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 needs to be corrected. The fee for the test would increase from \$32.11 to \$213.79, with the latter amount being necessary to recoup the department’s actual costs as called for in the cost calculation formula. The cost methodology used is as described in the Background and Purpose section in this preamble. The remaining subsections will be renumbered accordingly.

Existing §73.54(a)(2)(A)(vii), which would be renumbered as clause (vi), 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 accordingly.

Existing §73.54(a)(2)(A)(vii) is proposed to be further amended at existing subclause (XI) by updating the name of the test to *Neisseria* to more accurately identify the test and allow for typing of other species, and by updating the fee from \$390.52 to \$141.84. This reduction in fee is the cost of isolation only; identification is covered in the existing fee schedule under the definitive identification section.

Existing §73.54(a)(2)(A)(vii) is proposed to be further amended by inserting a new subclause (XVI) regarding a *Vibrio* test, at a price of \$228.15.

Existing §73.54(a)(2)(A)(xi) is proposed to be amended by decreasing the price from \$138.64 to \$91.58. This reduction in fee is the cost of isolation only; identification is covered in the existing fee schedule under the definitive identification section.

Existing §73.54(a)(2)(B) is proposed to be amended by inserting a new subclause (IV) regarding Lewisite metabolites in urine (2-chlorovinylarsonous acid (CVAA) and 2-chlorovinylarsonic acid (CVAOA), liquid chromatography, inductively coupled plasma mass spectrometry (LC-ICP-MS), at a cost of \$157.59. The subsection would be renumbered accordingly.

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 reduced 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)(C)(v) is proposed to be amended by the addition of two new subclauses: (IV) MGIT drug susceptibility test, primary panel; and (V) MGIT PZA susceptibility test, priced at \$115.05 and \$77.17, respectively.

Existing §73.54(a)(2)(E)(ii), (vii), (xiv)(I) and (xvi) are proposed to be amended by deleting the following low-volume tests: (ii) *Aspergillus*; (vii) Fungus; and (xiv) (I) HIV 1,2, plus 0 screen; and (xvi) Legionella. These tests are proposed for deletion to make more efficient use of laboratory staff and to lower operational costs.

Existing §73.54(a)(2)(E)(v), (ix), (x), (xix), (xxiii), (xxiv), (xxviii), and (xxx) are proposed to be amended by changing the price to reflect new technology: (v) cytomegalovirus (CMV): (I) IgG is reduced from \$399.97 to \$23.23; (II) IgM is reduced from \$161.02 to \$24.26; (ix) Hepatitis A: (I) IgM is reduced from \$317.74 to \$44.04; (II) total is reduced from \$219.60 to \$34.45; (x) Hepatitis B: (I) core antibody is reduced from \$143.90 to \$36.06; (II) core IgM antibody is reduced from \$295.64 to \$44.75; (III) surface antibody (Ab) is reduced from \$103.84 to \$28.34; (IV) surface antigen (Ag) is reduced from \$51.45 to \$18.47; (xix) Mumps: (I) epidemic parotitis IgG is reduced from \$154.46 to \$22.62; (xxii) Rubella: (I) IgM is reduced from \$329.37 to \$24.77; (II) Screen is reduced from \$24.13 to \$22.33; (xxiv) Rubeola: (II) screen (IgG) is reduced from \$165.16 to \$21.35; (xxviii) Toxoplasmosis is reduced from \$357.49 to \$23.23; and (xxx) *Varicella zoster* virus (VZV) is reduced from \$345.63 to \$19.70.

New §73.54(a)(2)(E)(xii) is proposed to be amended by the addition of a new subclause (II) that is necessary for a new test for HIV Combo Ag/AB EIA, priced at \$7.90. Existing §73.54(a)(2)(E)(xxi), which would be 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.

Existing §73.54(a)(2)(E)(xxvii) is proposed to be further amended by adding a new test to subclause (IV), Screening, IgG at a price of \$7.57.

In §73.54(a)(2)(F)(ii)(IV), a new test for the West Nile virus was added, priced at \$57.87.

Existing §73.54(a)(2)(F)(v)(I) is proposed to be amended by updating the name of the test to Supplemental Cell Culture to more accurately identify the test.

In §73.54(a)(2)(F)(vi) is proposed to be amended by the addition of a new test for Dengue, real-time, PCR, at a price of \$215.52.

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)(xi)(I) and (II). New §73.54(a)(2)(F)(xi)(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)(xi)(IV). Existing §73.54(a)(2)(F)(xiii) is proposed to be renumbered as §73.54(a)(2)(F)(xii). New §73.54(a)(2)(F)(xiii), (xiv) and (xv) are proposed to add a new test for Measles, real-time PCR for the amount of \$126.83, Mumps, real-time PCR for the amount of \$127.83 and a new text for Respiratory viral panel, PCR, for the amount of \$167.13.

Existing §73.54(a)(2)(F)(xv)(I) is proposed to be amended by updating the name of the test to “Viral isolation, clinical” to more accurately identify the test.

New §73.54(b)(1)(D) and (G) is proposed to be amended to add new tests--(D) Gram Stain, priced at \$8.06, and (G) Urine culture, priced at \$11.59. Existing tests in this subclause would be renumbered accordingly.

New §73.54(b)(2)(A) is proposed to add a new test, Alanine Amino Transferase (ALT), priced at \$1.34. New §73.54(b)(2)(F) is proposed to add a new test, Bilirubin, direct for \$1.69. New §73.54(b)(2)(H) is proposed to add a new test, Bilirubin, total & direct for \$2.44. New §73.54(b)(2)(R)(i) is proposed to add a new test, Glucose for \$1.34. Subsequent subsections are proposed to be renumbered accordingly.

Existing §73.54(b)(2)(M),(V), and (BB) are proposed to be amended by changing the names of the test for better clarity. (M) Electrolyte panel- includes anion gap (calculated), CO<sub>2</sub>, chloride, potassium and sodium will be renamed Electrolyte panel- includes CO<sub>2</sub>, chloride, potassium and sodium. (V) Lipid profile panel—includes, cholesterol, HDL, and triglycerides will be renamed Lipid profile panel— includes, cholesterol, HDL, LDL, and triglycerides. (BB) Renal function panel—includes albumin, calcium, CO<sub>2</sub>, chloride, creatinine, phosphate, potassium, sodium, and BUN will be renamed Renal function panel—includes albumin, glucose, calcium, CO<sub>2</sub>, chloride, creatinine, phosphate, potassium, sodium, and BUN.

New §73.54(b)(3) is a proposed new paragraph to add tests related to emergency preparedness with subclauses (A)- (D): (A) Biological Threat reference culture--\$198.28; (B) Definitive identification: (i) *Bacillus anthracis* --\$145.72; (ii) *Brucella* species--\$214.30; (iii) *Burkholderia* --\$221.62; (iv) *Francisella tularensis* --\$107.07; (v) *Yersinia pestis* --\$313.47; and (vi) Unknown biological threat agent--\$220.08; (C) Food Samples: (i) *Bacillus anthracis* \$--23.77; (ii) *Brucella* Species--\$25.77; (iii) *E. Coli* 0157:H7--\$7.15; (iv) *Francisella*--\$17.20; (v) *Listeria*--\$21.30; (vi) *Salmonella*--\$19.05; (vii) *Yersinia pestis*--\$313.47; (D) PCR: (i) *Bacillus anthracis* --\$58.41; (ii) *Brucella* --\$58.41; (iii) *Burkholderia* --\$58.41; (iv) *Francisella tularensis* --\$58.41; (v) *Influenza*--\$51.26; (vi) *Influenza A*--\$53.63; (viii) *Influenza A/H5*--\$125.00; (viii) Multiple Agent Panel--\$169.39; (ix) *Ricin*--\$150.00; and (x) *Yersinia pestis* --\$58.41. Existing §73.54(b)(3) - (7) are proposed to be renumbered as §73.54(b)(4) - (8).

Existing §73.54(b)(3)(F) is proposed to add a new test Peripheral Smear Review, priced at \$7.59 and renumber existing (F) to (G). Existing §73.54(b)(6)(A)(iii)(I) and (II) are updated to reflect new pricing: (I) conventional susceptibility (each drug) is reduced from \$36.45 to \$14.06, and (II) MGIT susceptibility (each drug) is reduced from \$92.69 to \$43.47. New §73.54(b)(6)(A)(iii) and (iv) are proposed to add a new tests (ii) (III) MGIT susceptibility (each Drug) PZA, priced at \$92.69, and (iv) for the Identification of AFB isolate, DNA probe, priced at \$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. New §73.54(b)(6) would add a new test to subclause (G) Thyroxine (T4), free, priced at \$10.89. Renumbering of §73.54(b)(6)(G) to (F) is proposed. Section 73.54(b)(6)(H) proposes to add a new test to the subclause, Thyroid Hormone (T3), uptake for \$23.67, with subsequent renumbering accordingly. New §73.54(b)(7)(D) and (G) proposes to add a new test, (D) Random urine/creatinine profile, for \$6.44 and (G) Urine Microscopic analysis for \$5.54. Subsequent subsections are proposed to be renumbered accordingly. Existing §73.54(b)(7)(F) and (J) are proposed to be renamed for better clarity. (F) Thyroxin (T4), free, prenatal will be renamed to Thyroxine (T4), total. (J) Tri-iodothyronine (T3), uptake, total, prenatal will be renamed Tri-iodothyronine (T3), free.

Existing §73.54 is proposed to be reorganized by removing subsection (c), which relates to tests performed on clinical specimens at the department's 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.

Existing §73.54(d)(4)(A)(iv) is proposed to add a new test for *Cronobacter sakazakii*, priced at \$115.17. New §73.54(d)(4)(A)(v)(II) is proposed by adding a new test for Non-0157 STEC, priced at \$295.02 and by reorganizing all tests related to *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 by adding a new test for West Nile Virus (WNV), mosquitoes, PCR, priced at \$57.87 in new §73.54(d)(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 low-volume tests are proposed for deletion to make more efficient use of laboratory staff and to lower operational 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.

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

Existing §73.55(2) is proposed to be amended by removing the phrase "including bottled water" to accurately reflect the testing. New §73.55(2)(C)(xiii) would add trihalomethanes, EPA method 551.1, priced at \$43.91. Subsequent subsections are proposed to be renumbered accordingly.

Section 73.55(3)(A)(x) is proposed to add a new test for gluten, priced at \$92.11, and existing §73.55(3)(A)(x) – (xx) are proposed to be renumbered as §73.55(3)(A)(xi) – (xxi) respectively.

Existing §73.55(3)(B)(ii)(I) is proposed to update pricing for mercury, EPA method 245.1 and EPA SW-846 methods 7470A and 7471B from \$192.35 to \$37.90. New pricing reflects increase in volume which reduces operational cost and increases efficiency.

Existing §73.55(4)(A)(iii)(I) is proposed to update pricing for mercury, sediment, EPA SW-846 method 7471B from \$194.22 to \$37.90. New pricing reflects increase in volume which reduces operational cost and increases efficiency.

Existing §73.55(5)(A)(i) is proposed to update pricing for fillets from \$34.56 to \$19.98. Existing §73.55(5)(B)(ii)(I) is proposed to update pricing for mercury, EPA method 7471B from \$192.35 to \$37.90. New pricing reflects increase in volume which reduces operational cost and increases efficiency.

Existing §73.55(6)(B)(ii)(II) is proposed to correct the price for the single metal, ICP, EPA method 200.7 and EPA SW-846 method 6010C for non-potable water. The fee would increase from \$67.49 to \$114.04. This increase in price is necessary because a clerical error was found in the existing rule text. The actual cost to perform the test is \$114.04. This is the price that is listed on the published fee schedule on the department's Laboratory website. The error in the rule text was clerical and must be corrected to ensure that the Laboratory recoups the department's actual costs as called for in the cost calculation formula. The cost methodology used is as described in the Background and Purpose section in this preamble. The remaining subsections will be renumbered accordingly.

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 Senate Bill (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 that the department recently realized through changes in technology. The correction to the *Bordetella pertussis*, *Parapertussis*, and *Bordetella holmesii* and single metal, ICP, EPA method 200.7 and EPA SW-846 method 6010C for non-potable water fees 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 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 two fees which would be increased, *Bordetella pertussis*, *Parapertussis*, and *Bordetella holmesii* detection by real-time polymerase chain reaction (PCR) and single metal, ICP, EPA method 200.7 and EPA SW-846 method 6010C for non-potable water. As discussed previously, that proposed increase is to correct a fee calculation error and clerical error in the previous rulemaking action, recently concluded, which updated the entirety of the LSS fee schedule consistent with SB 80. The corrected fee amounts would properly reflect the methodology used in that previous rulemaking action, which was designed to recoup the department's costs related to providing the service in its laboratories. Some of these proposed amendments would decrease other fee amounts for specific tests. The two fee increases 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 these increased fees 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 either of the two tests 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. Two fees went up (correcting a previous calculation error and clerical 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*" and single metal, ICP, EPA method 200.7 and EPA SW-846 method 6010C for non-potable water fees at their 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 fee corrections included in these proposed amendments to the rule were 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* and single metal, ICP, EPA method 200.7 and EPA SW-846 method 6010C for non-potable water fees 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's 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 financial 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* and single metal, ICP, EPA method 200.7 and EPA SW-846 method 6010C for non-potable water fees 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 Amy Schlabach, Laboratory Services Section, Mail Code 1947, P.O. Box 149347, Austin, Texas 78714-9347, (512) 776-6191 or by email at amy.schalabach@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 Government 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) Newborn screening.

(i) Newborn screening panel--\$33.60. (Fees are based on the newborn screening specimen collection kit which is a department approved, bar-coded, FDA approved medical specimen collection device that includes a filter paper collection device, parent information sheet, specimen storage and use information, parent disclosure request form, demographic information sheet, and specimen collection directions with protective wrap-around cover for the specimen that should be used to submit a newborn's blood specimen for the first or second screen, repeat or follow-up testing and which includes the cost of screening.)

(ii) Amino Acid Dietary Monitoring--\$16.61.

(iii) [(ii)] Phenylalanine/tyrosine--\$16.61.

(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) Aerobic isolation [**culture**] from clinical specimen--\$303.92 [**\$367.37**].

- (ii) (No change.)
- (iii) Anaerobic isolation [**culture**] from clinical specimen--\$118.39
- [\$197.10].**
- (iv) (No change.)
- [(v) Cholera, culture confirmation--\$32.73.]**
- (v) [(vi)] Culture, stool--\$158.07.
- (vi) [(vii)] Definitive identification:
- (I) bacillus--\$175.88;
  - (II) group B streptococcus (Beta strep)--\$113.70;
  - (III) *Bordetella* --\$147.77;
  - (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):
    - (-a-) GC/CT, amplified RNA probe--\$20.28;
    - (-b-) GC culture confirmation by amplified or direct probe--\$37.66; and
    - (-c-) GC screen--\$44.54.
  - (VIII) [(VII)] gram negative rod--\$261.00;
  - (IX) [(VIII)] gram positive rod--\$226.12;
  - (X) [(IX)] *Haemophilus*--\$242.23;
  - (XI) [(X)] *Legionella*--\$265.57;
  - (XII) [(XI)] *Neisseria [meningitides]*--\$141.84 [**\$390.52**];
  - (XIII) [(XII)] pertussis--\$287.98;
  - (XIV) [(XIII)] *Staphylococcus*--\$188.88; and

(XV) [~~(XIV)~~] *Streptococcus*--\$258.91.

(XVI) *Vibrio*--\$228.15.

(vii) - (ix) (No change.)

(x) [~~(xi)~~] *Haemophilus*:

(I) culture confirmation, serological--\$91.58 [~~\$138.64~~]; and

(II) isolation from clinical specimen--\$100.18.

(xi) [~~(xii)~~] *Neisseria meningitides*, serotyping--\$167.48.

(xii) [~~(xiii)~~] Shiga toxin producing *E.coli*, PCR--\$36.60.

(xiii) [~~(xiv)~~] Toxic shock syndrome toxin I assay (TSST 1)--  
\$125.25.

(B) Emergency preparedness.

(i) (No change.)

(ii) Chemical Threat agent Analysis

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

(IV) 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.

(V) [~~(IV)~~] Metabolic Toxin Panel (monochloroacetate and monofluoro acetate in urine, LC/MS-MS)--\$93.38.

(VI) [~~(V)~~] Metals in blood (mercury, lead, cadmium), inductively coupled plasma mass spectrometry (ICP/MS)--\$194.64.

(VII) [~~(VI)~~] Metals in urine (antimony, barium, beryllium, cadmium, cesium, cobalt, lead, molybdenum, platinum, titanium, tungsten, uranium), ICP/MS--\$173.25.

(VIII) [~~(VII)~~] Organophosphorus nerve agent, LC/MS-MS--\$81.28.

(IX) [~~(VIII)~~] Tetramine, gas chromatography/mass selective detector (GC/MSD)--\$183.05.

(X) [(IX)] Tetranitormethane metabolite in urine (4-hydroxy-2-nitrophenylacetic acid (HNPAAC)), liquid chromatography, tandem mass spectrometry (LC/MS-MS)--\$62.21.

(XI) [(X)] Volatile organic compounds in blood, GC/MS--\$124.85

(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) - (iv) (No change.)

(v) *Mycobacterium tuberculosis* (*M. tuberculosis*) complex drug susceptibility.

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

(IV) MGIT drug susceptibility test, primary panel--\$115.05.

(V) MGIT PZA susceptibility test--\$77.17.

(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--\$23.23 [**\$399.97**]; and

(II) IgM--\$24.26 [**\$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--\$44.04 [**\$317.74**]; and

(II) total--\$34.45 [**\$219.60**].

(viii) [(x)] Hepatitis B:

(I) core antibody--\$36.06 [**\$143.90**];

(II) core IgM antibody--\$44.75 [**\$295.64**];

(III) surface antibody (Ab)--\$28.34 [**\$103.84**]; and

(IV) surface antigen (Ag)--\$18.47 [**\$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;**

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

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

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

\$14.32;

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

(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--\$22.62 [**\$154.46**]; and

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

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

[\$84.45].

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

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

(xx) [(**xxiii**)] Rubella:

(I) IgM--\$24.77 [\$329.37]; and

(II) screen--\$22.33 [**\$24.13**].

(xxi) [(**xxiv**)] Rubeola:

(I) IgM--\$210.24; and

(II) screen (IgG)--\$21.35 [**\$165.16**].

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

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

(xxiv) [(xxvii)] Syphilis:

(I) Confirmation fluorescent treponemal antibody absorbed  
(FTA-ABS)--\$80.20;

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

(III) Rapid plasma reagin (RPR):

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

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

(IV) Screening, IgG--\$7.57.

(xxv) [(xxviii)] Toxoplasmosis--\$23.23 [**\$357.49**].

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

(xxvii) [(xxx)] Varicella zoster virus (VZV) [(VCV)]--\$19.70  
[**\$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) - (iv) (No change.)

(v) Culture:

(I) Supplemental Cell Culture [Clinical]--\$135.46; and

(II) reference--\$96.66.

(vi) Dengue, real-time PCR--\$215.52.

(vii) [(vi)] Echovirus, DFA--\$115.80.

(viii) [(vii)] Electron microscopy (includes observation, electron microscopy and photography)--\$527.91.

(ix) [(viii)] Enterovirus:

(I) DFA--\$162.96; and

(II) PCR--\$393.27.

(x) [(ix)] Herpes simplex virus 1 and 2, identification, DFA--\$96.52.

(xi) Influenza.

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

(II) [(xi)] Influenza surveillance with culture [Influenza, culture]--\$248.00.

(III) Influenza pyrosequencing for antiviral resistance--\$13.11.

(IV) [(xii)] Influenza surveillance without culture (typing, PCR)--\$131.32 [**\$248.00**].

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

(xiii) Measles, real-time PCR--\$126.83.

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

(xv) Respiratory viral panel, PCR--\$167.13.

(xvi) [(xiv)] Rotovirus, PCR--\$55.75.

(xvii) [(xv)] Viral agent:

(I) Viral isolation, clinical --\$172.70;  
\$147.83; and  
(II) indirect fluorescent antibody (IFA) detection, other--  
respiratory--\$95.34.

(xviii) [(xvi)] Viral molecular sequencing--\$400.65.

(xix) [(xvii)] Virus detection hemadsorption--\$42.18.

(xx) [(xviii)] Virus isolation, mouse inoculation--\$1029.50.

(xxi) [(xix)] Virus typing, hemagglutination inhibition--\$67.49.

(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) Bacteriology.

(A) - (C) (No change.)

(D) Gram Stain--\$8.06

(E) [(D)] KOH exam except for skin, hair nails--\$7.85.

(F) [(E)] Wet mount, vaginal--\$9.14.

(G) Urine culture--\$11.59

(2) Clinical Chemistry.

(A) Alanine Amino Transferase (ALT)--\$1.34.

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

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

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

(E) [(D)] Aspartate aminotransferase (AST)--\$1.32.

(F) Bilirubin, direct--\$1.69.

(G) [(E)] Bilirubin, total--\$1.30.

(H) Bilirubin, total& direct profile--\$2.44.

(I) [(F)] Blood urea nitrogen (BUN)--\$1.48.

(J) [(G)] Calcium--\$1.64.

(K) [(H)] Carbon dioxide (CO2)--\$1.35.

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

(M) [(J)] Cholesterol:

(i) total--\$1.36;

(ii) High-density lipoprotein (HDL)--\$1.37; and

(iii) Low-density lipoprotein (LDL)--\$2.20.

(N) [(K)] Creatine kinase (CK) assay--\$2.79.

(O) [(L)] Creatinine assay--\$1.30.

(P) [(M)] Electrolyte panel—includes [**anion gap (calculated),**] CO2, chloride, potassium, and sodium--\$2.83.

(Q) [(N)] Gamma-glutamyl transferase (GGT)--\$3.90.

(R) [(O)] Glucose:

(i) Glucose--\$1.34;

(ii)[(i)] Glucose tolerance test, 2 hour--\$1.37; and

(iii)[(ii)] postprandial, 0 and 2 hours--\$1.34.

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

(T) [(Q)] Hemoglobin A1C--\$10.37.

(U) [(R)] Iron binding capacity, total--\$8.55.

(V) [(S)] Iron, total--\$7.08.

(W) [(T)] Lactic acid dehydrogenase (LDH)--\$8.17.

(X) [(U)] Lipase--\$20.43.

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

(Z) [(W)] Magnesium--\$7.82.

(AA) [(X)] Metabolic panels:

(i) basic panel--includes calcium, carbon dioxide (CO<sub>2</sub>), chloride, creatinine, glucose, potassium, sodium and blood urea nitrogen (BUN)--\$3.65; and

(ii) comprehensive panel--includes alanine amino transferase (ALT), albumin, alkaline phosphatase, AST, bilirubin (total), calcium, CO<sub>2</sub>, chloride, creatinine, glucose, potassium, protein (total), sodium, and BUN--\$6.39.

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

(CC) [(Z)] Potassium--\$1.35.

(DD) [(AA)] Protein, total--\$1.41.

(EE) [(BB)] Renal function panel--includes albumin, glucose, calcium, CO<sub>2</sub>, chloride, creatinine, phosphate, potassium, sodium, and BUN--\$18.13.

(FF) [(CC)] Sodium--\$1.35.

(GG) [(DD)] Triglycerides--\$1.36.

(HH) [(EE)] Tuberculosis panel--includes-ALT, alkaline phosphatase, AST, bilirubin (total), cholesterol, creatinine, GGT, BUN, and uric acid (blood)--\$10.36.

(II) [(FF)] Uric acid--\$4.07.

(3) Emergency Preparedness.

(A) Biological Threat reference culture--\$198.28.

(B) Definitive identification.

(i) *Bacillus anthracis*--\$145.72.

(ii) *Brucella* species--\$214.30.

(iii) *Burkholderia*--\$221.62.

(iv) Francisella tularensis--\$107.07.

(v) Yersinia pestis--\$313.47.

(vi) Unknown biological threat agent--\$220.08.

(C) Food samples.

(i) Bacillus anthracis--\$23.77.

(ii) Brucella Species--\$25.77.

(iii) E.Coli 0157:H7--\$7.15.

(iv) Francisella--\$17.20.

(v) Listeria--\$21.30.

(vi) Salmonella--\$19.05.

(vii) Yersinia pestis--\$313.47.

(D) PCR.

(i) Bacillus anthracis--\$58.41.

(ii) Brucella--\$58.41.

(iii) Burkholderia--\$58.41.

(iv) Francisella tularensis--\$58.41.

(v) Influenza--\$51.26;

(vi) Influenza A--\$53.63;

(vii) Influenza A/H5--\$125.00;

(viii) Multiple Agent Panel--\$169.39;

(ix) Ricin--\$150.00; and

(x) Yersinia pestis --\$58.41.

(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) Peripheral Smear Review--\$7.59.

(G) [(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)--\$14.06;

**[\$36.45; and]**

(II) MGIT susceptibility (each drug)--\$43.47; and [\$92.69.]

(III) MGIT susceptibility (each drug) PZA--\$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.

\$67.17.

(B) Parasitology, ova and parasites (concentration and trichrome stain)--

(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) Thyroxine (T4), free--\$10.89.

(G) Thyroxine (T4), total--\$35.53.

(H) Thyroid Hormone (T3) uptake--\$23.67.

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

(J) Tri-iodothyronine (T3), free--\$19.10.

**[(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) Random Urine/Creatinine Profile--\$6.44.
- (E) [(D)]Urinalysis, no reflex--\$5.24.
- (F) [(E)] Urine microalbumin, random--\$5.69.
- (G) Urine Microscopic Analysis--\$5.54.

**[(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.]**

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

**\$47.58.]**

**[(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*--\$115.17.

(v) *Escherichia coli*.

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

(II) Non-0157 STEC--\$295.02.

(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) Analysis of volatile organic compounds in air (charcoal tubes), National Institute for Occupational Safety and Health NIOSH method--\$127.24.

(2) The following fees apply to analysis of drinking water [(including bottled water)] samples.

(A) - (B) (No change)

(C) Organic compounds:

(i) - (xi) (No change.)

(xii) trihalomethanes, EPA methods 502.2 or 524.2--\$50.13; **[and]**

(xiii) trihalomethanes, EPA method 551.1--\$43.91; and

(xiv) [(xiii)] volatile organic compounds VOCs by GC-MS, EPA method 542.2--\$55.12.

(D) (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) Metals analyses. A sample preparation fee applies to all food samples analyzed by ICP or ICP-MS techniques. A sample requiring both ICP and ICP-MS techniques will require two sample preparations. The total analysis fee includes the sample preparation fees and the per-element fee. The fee for analysis of multiple metals by a single method includes a single sample preparation fee and the appropriate per-element fees.

(i) Sample preparation fee--total recoverable metals digestion, EPA methods 200.2, 200.3, or SW-846 method 3050B--\$22.88.

(ii) Per-element fees:

(I) mercury, EPA method 245.1 and EPA SW-846 methods 7470A and 7471B--\$37.90 [**\$192.35**];

(II) - (III) (No change.)

(4) The following fees apply to the analysis of soil and solids.

(A) Metals analysis. A sample preparation fee applies to the analysis of all solid (soil, sediment, etc.) samples. A sample requiring both ICP and ICP-MS techniques will require two sample preparations. The total cost of the analysis will be the sample preparation fees plus the per-element fee. The fee for analysis of multiple metals by a single method includes a single sample preparation fee and the appropriate per-element fees. Determination of leachable metals in solid samples will require a solid leachate sample preparation procedure, as well as analysis of the leachate using non-potable water analytical methods. The total cost of the analysis will be the solid leachate sample preparation fee plus the required non-potable water preparation fee(s) and the per-element test(s).

(i) Sample preparation fee--acid digestion of sediments, sludges, and soils, EPA SW-846 Method 3050B--\$84.92.

(ii) Solid leachate for metals--\$273.88.

(iii) Per-element fee:

(I) mercury, sediment, EPA SW-846 method 7471B--\$37.90 [**\$194.22**];

(II) - (III) (No change.)

(B) (No change.)

(5) The following fees apply to the analysis of tissue and vegetation samples. A tissue preparation (homogenization) fee applies to all seafood tissue samples analyzed for metals. The total analysis cost includes the tissue preparation fee, any analyte specific sample preparation fee, and the per-element or per-group test fee.

(A) Tissue preparation fees:

(i) fillets--~~\$19.98~~ [**\$34.56**]; and

(ii) whole fish and crabs--\$46.08.

(B) Metals analyses. A sample preparation fee applies to all tissue samples analyzed by ICP or ICP-MS. The total analysis cost includes the per-element or per-group fee plus any required sample preparation fee:

(i) sample preparation fee--total recoverable metals digestion, EPA method 200.3--\$22.88;

(ii) per-element fees:

(I) mercury, EPA method 7471B--~~\$37.90~~ [**\$192.35**];

(II) - (III) (No change.)

(C) (No change.)

(6) The following fees apply to the analysis of non-potable water.

(A) (No change.)

(B) Metals analysis. The following sample preparation fees apply to the analysis of non-potable water samples. A sample requiring both ICP and ICP-MS techniques will require two sample preparations. The total cost of the analysis will be the required sample preparation fee(s) plus the per-element fee. The fee for analysis of multiple metals by a single method includes a single sample preparation fee and the appropriate per-element fees.

(i) (No change.)

(ii) Per-element fees:

(I) mercury, EPA method 245.1 and EPA SW-846 method 7470A--  
-\$28.10;

(II) single metal, ICP, EPA method 200.7 and EPA SW-846 method 6010C--\$114.04 [**\$67.49**]; and

(III) single metal, ICP-MS, EPA method 200.8, and EPA SW-846 method 6020A--\$67.49.

(C) (No change.)

(7) - (8) (No change.)

(9) Additional charges.

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

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