

**RULEMAKING NOTICE FORM**

Notice Number 2016-5

Rule Number He-P 2205

1. Agency Name & Address:  
**NH Dept. of Health & Human Services  
Bureau of Licensing and Certification  
Health Facility Licensing Unit  
129 Pleasant Street  
Concord, NH 03301**

2. RSA Authority: RSA 131:4  
3. Federal Authority: \_\_\_\_\_  
4. Type of Action:  
Adoption \_\_\_\_\_  
Amendment \_\_\_\_\_  
Repeal \_\_\_\_\_  
Readoption \_\_\_\_\_  
Readoption w/amendment X

5. Short Title: **Public Health Laboratories Fee Schedule**

6. (a) Summary of what the rule says and of any proposed amendments:  
**He-P 2205 establishes the fees for laboratory tests performed by the Public Health Laboratories (PHL). The current interim rules expire on March 20, 2016.**

**The proposal amends the fee schedule by adding fees for new tests, deleting fees for discontinued tests, and adjusting fees for tests which employ new technology or have increased complexity. Some of the changes made in the proposed rules include: deletion of tests and fees for tests which are no longer performed due to changes in technology, reduced demand, or because the test no longer has diagnostic or public health value. Fees are being added or increased for tests where new technology either replaces existing technology, is more complex than existing technology, creates new testing platforms that are more specific, or which can test for multiple chemicals or organisms at the same time. Additional fees are added for new tests that aid in rapid diagnostics for highly infectious diseases. The proposed rules include fees based on current procedural terminology (CPT) codes, and amends fees to align with testing activity and changes in technology and nomenclature. The new fees are based on current fees for similar tests.**

**PHL services include conducting testing related to disease outbreaks, surveillance, and other public health events of concern. PHL has a specially equipped facility and trained staff to test for highly infectious diseases such as rabies and tuberculosis, and performs testing of food, such as shellfish to monitor Red Tide events, and dairy products to assure product safety. The proposed rules will allow PHL to continue to effectively administer laboratory services and assess fees for the testing it performs for Department of Health and Human Services (DHHS) programs, other state agencies, healthcare providers, and others requiring its specialized facilities and staff expertise.**

6. (b) Brief description of the groups affected:  
**Those affected by the proposed rules include groups and individuals who rely on PHL testing and who are billed according to the fees listed in He-P 2205. Some of the groups affected include DHHS programs for infectious disease control, such as human immunodeficiency virus (HIV), sexually transmitted disease (STD), and tuberculosis (TB), prevention programs, and other state agencies including the NH Medical Examiner’s Office, the Department of Corrections, the NH Estuaries Project, and dairy and shellfish producers.**

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

<u>Rule</u>	<u>Federal Reg./RSA</u>
He-P 2205.01- 2205.05	RSA 131.4

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name: **Catherine Bernhard** Title: **Rules Coordinator**  
Address: **Dept. of Health and Human Services** Phone #: **271-9374**  
**Administrative Rules Unit** Fax#: **271-5590**  
**129 Pleasant St.** E-mail: [catherine.bernhard@dhhs.state.nh.us](mailto:catherine.bernhard@dhhs.state.nh.us)  
**Concord, NH 03301**

TTY/TDD Access: Relay NH 1-800-735-2964 or dial 711 (in NH)

**The proposed rules may be viewed and downloaded at:**

<http://www.dhhs.nh.gov/oos/aru/comment.htm>

8. Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: **Thursday, February 25, 2016**

Fax  E-mail  Other format (specify):

9. Public hearing scheduled for:

Date and Time: **Thursday, February 18, 2016 at 2:30 PM**

Place: [\*\*DHHS Brown Bldg., Room 232, 129 Pleasant St., Concord, NH\*\*](#)

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant)

FIS # 15:228, dated 01/07/16

**1. Comparison of the costs of the proposed rule(s) to the existing rule(s):**

When compared to the existing rules, the proposed rules will have an indeterminable impact on costs for state citizens, costs for independently owned businesses and on state general fund revenue.

**2. Cite the Federal mandate. Identify the impact of state funds:**

No federal mandate, no impact on state funds.

**3. Cost and benefits of the proposed rule(s):**

The proposed rule establishes fees for laboratory tests performed by the Public Health Laboratories (PHL). The proposed rules include the following changes: certain tests are being deleted and will no longer be performed due to changing technology; reduced demand for the tests; or because the test no longer has diagnostic or public health value. In addition, other tests are being added due to new technology that replaces existing technology, creates new testing platforms that are more specific, can test for multiple chemicals or organisms at the same time, or aids in rapid diagnostics for highly infectious diseases. In addition, the proposed rule adjusts fees for existing tests employing new technology. The proposed rules will affect groups and individuals who rely on PHL testing and who are billed according to the fees listed in the rule, although the impact is indeterminable as some fees are being increased, some fees are being decreased, some new tests are being added, and some existing tests are being discontinued. To the extent state citizens and independently owned businesses utilize the laboratory testing services identified in the rules, they will have an indeterminable impact on their costs.

**A. To State general or State special funds:**

Fee revenue generated from the tests identified in the rule is deposited in the state general fund. The Department is unable to predict the impact of the various fee changes. For informational purposes, the Department notes that in 2015, revenue of \$322,369 was generated from fees assessed by the PHL for its services.

**B. To State citizens and political subdivisions:**

See response to (3) above. No impact on political subdivisions.

**C. To independently owned businesses:**

See response to (3) above.

11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

**The proposed rules modify an existing program or responsibility, but do not mandate any fees, duties or expenditures on the political subdivisions of the state, and therefore do not violate Part I, Article 28-a of the N.H. Constitution.**

Readopt with amendment He-P 2205, effective 9-22-15 (Document # 10935), to read as follows:

PART He-P 2205 LABORATORY FEE SCHEDULE

He-P 2205.01 Clinical Specimens, Chemistry. The following fees shall be charged for those clinical specimens set forth in Table He-P 2205.01 Chemistry below:

Table He-P 2205.01 Chemistry

<u>TEST</u>	<u>FEE</u>
<del>Arsenic, blood, quantitative</del>	<del>65.00</del>
<del>Arsenic (total), urine, quantitative</del>	<del>50.00-25.00</del>
<del>Metals panel, urine</del>	<del>50.00/hr.</del>
<u>Barium</u>	<u>25.00</u>
<u>Beryllium</u>	<u>25.00</u>
<del>Cadmium, urine</del>	<del>25.00-50.00/hr.</del>
<u>Cadmium, blood</u>	<u>25.00</u>
<del>Copper, serum</del>	<del>50.00/hr.</del>
<del>Copper, urine</del>	<del>50.00/hr.</del>
<del>Creatinine, other source (spot), urine</del>	<del>15.00+0.00</del>
<del>Cyanide, blood</del>	<del>80.00+40.00</del>
<del>Erythrocyte protoporphyrin, quantitative</del>	<del>10.00</del>
<del>Heavy Metal Screen</del>	<del>50.00/hr.</del>
<del>Lead, blood</del>	<del>25.00-22.00</del>
<del>Mercury, blood quantitative</del>	<del>25.00+80.00</del>
<u>Mercury urine</u>	<u>50.00</u>
<del>Mercury, urine, quantitative</del>	<del>80.00</del>
<u>Metals panel, blood</u>	<u>75.00</u>
<u>Metals panel, urine</u>	<u>100.00</u>
Miscellaneous analysis	50.00/hr
<u>Speciated arsenic, urine</u>	<u>125.00</u>
<u>Thallium</u>	<u>25.00</u>
<u>Volatile Organic Compounds, serum</u>	<u>80.00</u>

He-P 2205.02 Clinical Specimens, Microbiology. The following fees shall be charged for those clinical specimens set forth in Table He-P 2205.02 Microbiology below:

**Table He-P 2205.02 Microbiology/Virology**

<b>TEST</b>	<b>FEE</b>
Adenovirus – culture	50.00
Adenovirus – immunofluorescent, each antisera	20.00
Bacterial culture, blood, aerobic	28.00
Bacterial culture, urine	28.00
Bacterial culture, other, aerobic	28.00
Bacterial culture, other, anaerobic	28.00
Bacteria, identification, per isolate, aerobic	21.00
Bacteria, identification, per isolate, anaerobic	21.00
<u>Bacterial identification – 16S rRNA Sequencing</u>	<u>159.00</u>
<u>Bordetella pertussis, PCR</u>	<u>150.28.00</u>
<u>Bordetella pertussis positive confirmation, PCR</u>	84.00
<u>Bordetella pertussis diluted repeats, PCR</u>	64.00
<u>Chikungunya virus RT-PCR</u>	<u>50.00</u>
Chlamydia culture	50.00
Chlamydia immunofluorescent, each antisera	20.00
Chlamydia trachomatis, amplified method	25.00
Cryptosporidium/Giardia , DFA	35.00
Cryptococcus latex agglutination	25.00
<u>Cytomegalovirus (CMV) culture</u>	<u>50.00</u>
<u>Cytomegalovirus (CMV), immunofluorescent, each antisera</u>	<u>20.00</u>
Diphtheria culture	35.00
Direct smear, simple stain	21.00
<u>Eastern Equine Encephalitis (EEE) Virus Antibodies, IgG</u>	<u>35.00</u>
Eastern Equine Encephalitis (EEE) Virus Antibodies, IgM	35.00
Enteric pathogen culture, stool (single organism)	21.00
Enteric pathogen culture, stool (Salmonella and Shigella)	21.00
Enteric pathogen culture (comprehensive – includes SLT test)	50.00
Enteric isolate for identification, per aerobic isolate	21.00
Enteric isolate for identification, per anaerobic isolate	21.00
Enterovirus culture	50.00
Enterovirus immunofluorescent, each antisera	20.00
<u>Enterovirus RT-PCR</u>	<u>50.00</u>
Enzyme immunoassay, per specimen	18.00
Fluorescent Antibody Tests, Direct	15.00
Gonorrhea culture	21.00
<u>Hantavirus, IgG and IgM</u>	<u>-60.00</u>
Hepatitis A antibody – total	30.00
Hepatitis A IgM antibody	30.00
Hepatitis B surface antigen	30.00
Hepatitis B surface antibody	30.00
Hepatitis B core antibody – total	30.00
Hepatitis B core antibody IgM	30.00
Hepatitis B - other marker	50.00
Hepatitis C antibody <del>screen</del>	30.00
<u>Hepatitis C RNA Quantitative</u>	<u>125.00</u>

<u>Hepatitis C Virus Genotyping, Sequencing Method</u>	159.00
<del>Hepatitis C amplified method</del>	<del>100.00</del>
<del>Hepatitis C RIBA</del>	<del>100.00</del>
Herpes simplex culture	50.00
Herpes simplex immunofluorescent, each antisera	20.00
Herpes simplex DFA, type 1	20.00
Herpes simplex DFA, type 2	20.00
Herpes simplex, type 1 antibody	30.00
Herpes simplex, type 2 antibody	30.00
<del>Human Immunodeficiency Virus – 1 (HIV-1), antibody</del>	<del>25.00</del>
Human Immunodeficiency Virus –1 and 2 antibody, single assay	40.00
<u>Human Immunodeficiency Virus – 1 and 2 antibody, P24 antigen</u>	<u>40.00</u>
<u>Human Immunodeficiency Virus – 1 and 2 antibody differentiation</u>	<u>50.00</u>
<del>Human Immunodeficiency Virus (HIV) confirmatory test by Western Blot</del>	<del>50.00</del>
Infectious agent screen – other	35.00
Influenza culture	75.00
Influenza immunofluorescent, each antisera	20.00
<u>Influenza A/B, PCR</u>	<u>100</u> <del>95.00</del>
<u>Influenza Subtyping, PCR</u>	<u>200</u> <del>112.00</del>
Legionella culture	40.00
Legionella DFA	10.00
Legionella referred isolate	40.00
<del>Legionella urinary antigen</del>	<del>25.00</del>
<del>Lyme Disease antibodies ELISA— IgG and IgM</del>	<del>25.00</del>
<del>Lyme Disease confirmatory test by Western Blot, each assay</del>	<del>50.00</del>
Measles (Rubeola) IgG antibody (Immune Status)	25.00
Measles (Rubeola) IgM antibody	30.00
<u>Measles virus RNA</u>	<u>105.00</u>
<u>MERS CoV RT-PCR</u>	<u>50.00</u>
Mumps culture	50.00
Mumps immunofluorescent, each antisera	20.00
Mumps IgG antibody	25.00
<u>Mumps IgM antibody</u>	<u>25.00</u>
<u>Mumps virus RNA</u>	<u>50.00</u>
Mycobacteria isolate identification	85.00
Mycobacteria (AFB) smear	10.00
Mycobacteria (AFB) <del>smear and</del> culture	<del>35.00</del> <u>45.00</u>
<u>Mycobacterium tuberculosis direct probe</u>	<u>150.00</u>
<i>Mycobacterium tuberculosis</i> susceptibility – first line drugs, each drug	25.00
Mycology culture, blood	35.00
Mycology culture, skin, hair or nails	35.00
Mycology culture, other	35.00
Mycology yeast identification, per isolate	50.00
Mycology non-yeast identification, per isolate	50.00
Mycology contaminated isolates (charged in addition to identification fee)	20.00
<i>Neisseria gonorrhoea</i> , amplified method	25.00
<u>Norovirus, PCR</u>	<u>100</u> <del>83.00</del>
Parainfluenza culture	50.00
Parainfluenza virus immunofluorescent, each antisera	20.00

Parasitology, blood/tissue parasites	43.00
Parasitology, stool for ova & parasite	89.00
Parasitology, worm <u>i</u> dentification	13.00
Parasitology, modified acid fast stain for Cyclospora, Isospora and Sarcocystis	43.00
Parasitology, Microsporidium, modified trichrome blue stain	70.00
<del>Parvovirus B19, IgG and IgM</del>	<del>-25.00</del>
Pertussis culture	40.00
<u>Phlebotomy-Capillary</u>	<u>10.00</u>
<u>Phlebotomy-Venipuncture</u>	<u>10.00</u>
Pneumocystis jiroveci (carinii) DFA	35.00
Pulsed field gel electrophoresis (PFGE), per isolate	125.00
Rabies (no public health risk)	175.00
<u>Respiratory virus panel, amplified method</u>	<u>300.00</u>
<u>Respiratory virus culture</u>	<u>50.00</u>
<u>Respiratory virus immunofluorescent, each antisera</u>	<u>20.00</u>
Respiratory syncytial virus (RSV) culture	50.00
Respiratory syncytial virus (RSV) immunofluorescent, each antisera	20.00
Respiratory syncytial virus (RSV) DFA	20.00
Rubella antibody, IgG	25.00
Rubella antibody, IgM	30.00
Serogrouping, Shigella species	45.00
Serotyping, Salmonella species	50.00
Serotyping, <i>Neisseria meningitidis</i>	66.00
Serotyping, <i>Haemophilus influenzae</i>	66.00
Serotyping, Vibrio cholera serotyping	45.00
Serotyping, Enterohemorrhagic <i>Escherichia coli</i>	66.00
Shiga-like Toxin screen	40.00
Shiga Toxin (STEC), PCR	91.00
<u>Specimen to Reference Lab/CDC</u>	<u>Cost of test shipping.</u>
<del>St. Louis Encephalitis virus antibodies, IgG</del>	<del>35.00</del>
St. Louis Encephalitis virus antibodies, IgM	35.00
Susceptibility testing - Kirby Bauer (up to 12 disks)	25.00
Susceptibility testing – E-test, per drug	10.00
Susceptibility testing, fungal, per drug	59.00
Syphilis, qualitative	15.00
Syphilis, quantitative	25.00
Syphilis, confirmatory	30.00
Toxin assay	40.00
Varicella zoster virus culture	50.00
Varicella zoster virus immunofluorescent, each antisera	20.00
Varicella zoster virus DFA	20.00
Varicella zoster antibody	35.00
Virus culture - other	50.00
Virus culture immunofluorescent	20.00
Western Blot, other than HIV	60.00
<del>West Nile Virus (WNV), IgG</del>	<del>35.00</del>
West Nile Virus (WNV), IgM	35.00
<del>Specimen to Reference Lab/CDC</del>	<del>Cost of test plus shipping</del>
<del>Norovirus, PCR</del>	<del>83.00</del>

Influenza A/B, PCR	195.00
Influenza Subtyping, PCR	112.00
<i>Bordetella pertussis</i> , PCR	128.00
<i>Bordetella pertussis</i> positive confirmation, PCR	84.00
<i>Bordetella pertussis</i> diluted repeats, PCR	64.00
Mumps, PCR	105.00
Shiga Toxin (STEC), PCR	91.00
Ribotyping	97.00
Pulsed Field Gel Electrophoresis	154.00
Rep-PCR	158.00
Hepatitis C Virus Genotyping, 3 <sup>rd</sup> Wave Method	158.00
Hepatitis C Virus Genotyping, Sequencing Method	159.00
MDX - DNA or RNA isolation	6.00
MDX - DNA or RNA purification	15.00
MDX – restriction enzyme digestion, per reaction	6.00
MDX – gel electrophoresis, per lane (reaction)	6.00
MDX – nucleic acid probe, each	6.00
<del>MDX – nucleic acid transfer</del>	<del>6.00</del>
<u>MDX – single PCR amplification</u>	<u>16.00</u>
<del>MDX – single PCR amplification</del>	<del>16.00</del>
MDX – duplex PCR amplification	32.00
MDX – multiplex PCR amplification, each additional after duplex	16.00
MDX – reverse transcription	14.00
MDX – cell lysis prior to isolation or purification	12.00
MDX – interpretation and reporting	20.00
<del>MDX – complex separation</del>	<del>20.00</del>
MDX - miscellaneous	75.00/hr

He-P 2205.03 Occupational and Environmental Health Samples. The following fees shall be charged for those occupational and environmental health samples set forth in Table He-P 22005.03 Occupational and Environmental below:

**Table He-P 22005.03 Occupational and Environmental**

<b>TEST</b>	<b>FEE</b>
<del>Lead or Cadmium – paint, or release from pottery glaze or decorative glasses</del>	<del>-25.00</del>
Lead, maple syrup	40.00
<del>Lead, soil, or bioavailable from dust</del>	<del>-25.00</del>
<del>Miscellaneous analysis</del>	<del>-50.00/hr</del>

He-P 2205.04 Consumer Protection Samples. The following fees shall be charged for those consumer protection samples set forth in Table He-P 22005.04 Consumer Protection below:

**Table He-P 22005.04 Consumer Protection**

<b>TEST</b>	<b>FEE</b>
Food - Complete bacterial analysis	100.00
Food - Coliform count, total and fecal, Most Probable Number (MPN)	60.00
Food - Pathogen screen, per organism	40.00



Food - Foreign object	25.00
Food - pH	7.50
Food - Standard plate count	35.00
Food - Complete bacterial analysis, quality only	50.00
Food – Staphylococcus Culture	35.00
Food - Water activity	7.50
Milk or Cream - Complete analysis	25.00
Milk or Cream - Antibiotics, per group	10.00
Milk or Cream - Butterfat content	11.00
Milk or Cream - Coliform count	10.00
Milk or Cream - Direct Microscopic Somatic Cell Count (DMSCC)	18.00
Milk or Cream - Pathogen screen, per organism	40.00
Milk or Cream - Standard plate count	10.00
Milk or Cream - Total solids	8.00
Milk or Cream - Dairy waters	21.00
Milk or Cream - Phosphatase	8.00
Milk or Cream - Vitamin A or D	50.00
Milk or Cream - Added water	10.00
Milk or cream – Container analysis	15.00
Miscellaneous analysis	50.00/hr
<del>Seawaters, complete bacterial analysis</del>	<del>60.00</del>
<del>Seawaters – Fecal coliform</del>	<del>46.00</del>
<del>Seawaters – pH</del>	<del>7.00</del>
<del>Seawaters – Salinity</del>	<del>7.00</del>
Shellfish - Complete bacterial analysis	70.00
Shellfish - Fecal coliform count, (MPN )	60.00
Shellfish - Standard plate count	50.00
Shellfish - Microorganism identification	40.00
Shellfish Toxin Assay (e.g. PSP)	200.00
<u>Shellfish – Vibrio Analysis (PCR-MPN)</u>	<u>150.00</u>
Toxin assay, misc.	75.00

He-P 2205.05 Addition of Tests to Fee Schedule. Pursuant to RSA 141-C:19 laboratory tests shall be added to the fee schedule if any one or more of the following occurs:

- (a) The test is required by law;
- (b) The test is required to support the work of the division and other state agencies; and
- (c) The test is required to protect the public health of New Hampshire, and is not readily available to other locations within the state.

#### APPENDIX

<b>RULE</b>	<b>STATUTE</b>
He-P 2205.01 – 2205.05	RSA 131:4