

New Jersey Department of Health and Senior Services
Clinical Laboratory Improvement Services

www.nj.gov/health/phel/clis.shtml

(Telephone: 609-406-6830 Fax: 609-406-6863)

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Trenton, NJ 08625-0361

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3 Schwarzkopf Drive
Ewing, NJ 08628

**GENERAL INSTRUCTIONS FOR COMPLETING AN
APPLICATION FOR LICENSURE OF A CLINICAL LABORATORY
(UNDER THE PROVISIONS OF N.J.S.A. 45:9-42.26 ET SEQ.)**

NOTICE TO ALL APPLICANTS FOR A CLINICAL LABORATORY LICENSE:

Under the provisions of N.J.S.A. 45:9-42.26 et seq. and N.J.A.C. 8:44, the signed Application for Licensure of a Clinical Laboratory, and all requested attachments, must be completed in full and returned to the above address with the appropriate fee. Fees are non-refundable and incomplete applications will not be processed.

Checks or money orders should be made payable to the "New Jersey Department of Health and Senior Services" (NJDHSS) and include the CLIS ID Number for all renewals.

INITIAL LICENSURE PROCESS [Check appropriate box on top of page one of application (CL-3)]:

1. Submit completed license application (CL-3) and materials below to CLIS with the appropriate fees.
2. Submit ownership form (CL-9).
3. Ensure that Laboratory Director is licensed by the Board of Medical Examiners as a Bioanalytical Laboratory Director and submit proof of license.
4. Submit completed Personnel Qualification Appraisal forms (CL-34) for the following:
 - Laboratory Director
 - Technical Supervisor(s)
 - General Supervisor(s)
 - Testing personnel

Evaluate that personnel meet state personnel requirements. If the laboratory director is not a clinical pathologist, you are required to have a technical supervisor who meets the requirements of N.J.A.C. 8:44-2.5 (c) for all requested specialties.

5. Have a general supervisor who meets the requirements of N.J.A.C. 8:44-2.4 (c) for all requested specialties and is on the laboratory premises during all hours in which tests are routinely performed
6. Submit description and plan of the premises to be occupied for the operation of the laboratory.
7. Demonstrate test performance competency by submitting either documentation of successful participation in an approved proficiency testing survey or, when an acceptable proficiency survey is unavailable, provide acceptable validation documentation for each test and/or examination offered to clients.
8. For laboratories located outside of New Jersey, which are seeking licensure because they operate collection stations in New Jersey, submit a copy of an on-site survey report performed by a regulatory agency.

A license issued under N.J.S.A. 45:9-42.26 et seq. and N.J.A.C. 8:44 IS NOT TRANSFERABLE. A new application must be submitted if there is a change in ownership.

A new license shall be obtained whenever the name or location of a clinical laboratory is changed. **The NJDHSS must be notified by certified mail within fourteen days of such changes and include a \$100 fee.**

The license shall be conspicuously displayed by the licensee on the laboratory premises.

ANNUAL RENEWAL OF LICENSURE (Check appropriate box on top of page one):

All clinical laboratory licenses shall be issued on or before January 1 of each calendar year and shall expire on December 31 of each calendar year.

The NJDHSS will provide applications for licensure renewal on or before October 1 of each year to be properly completed and returned to the Department, together with the appropriate licensure renewal fee, **no later than November 1.**

**SPECIFIC INSTRUCTIONS FOR COMPLETING THE CL-3
APPLICATION FOR LICENSURE OF A CLINICAL LABORATORY
FOR CALENDAR YEAR 2012**

When completing your license application, please pay particular attention to the following:

Page 1:

1. In the upper right corner, fill-in the current year CY-2012 for this year's application.
2. Complete the type of application, i.e., initial or renewal.
3. Indicate the actual name and address of the laboratory that will appear on the license.
4. Each licensed laboratory is assigned a unique state-issued **CLIS ID Number** which is located on the top right hand corner of your current license. When applying for your **renewal** license, please include this number in the assigned box on all renewal applications and on your check or money order.
5. The CLIA number is the unique federal laboratory certification number that for NJ begins with 31D0 or 31D1 followed by 6 numbers.
6. Name the contact person, the laboratory's phone number, facsimile number and E-mail address.
7. Parent laboratory is defined as the site where all correspondence is sent and to which patient specimens are transported from the licensed collection stations. Include the city where the parent laboratory is located.

Entities having multiple testing sites would indicate one site as the parent site.

8. Normal hours of laboratory operation (page 1): This pertains to laboratory-associated activities only, i.e., the collection and/or testing of patient specimens and reporting of test results. It does not pertain to the normal business hours of the facility in which the laboratory is located.
9. Indicate your type of laboratory.
10. Indicate your type of CLIA Certification.
11. Ownership section (page 1): You must include anyone owning 5% or more having direct or indirect ownership interests or controlling interest, and define the corporate structure.

Initial applicants: Please submit the Ownership and Controlling Interest Disclosure Statement (Form CL-9).

12. Information on the laboratory director: **List home address of director (not laboratory address)**, specific days and hours on the premises at the applicant site and any other testing site(s) within and outside of New Jersey must be included.

Page 2:

13. Laboratory Personnel

We are requesting that you submit a listing of your current laboratory personnel using one of the following: submit a CD containing the information on page 2 of the CL-3 form; complete page 2 of the CL-3 form; or send the Excel spreadsheet available on our website just below the CL-3 link to: clislicensing@njlincs.net

General Supervisor vs. Technical Supervisor: **A qualified General Supervisor must be on the laboratory premises during all regularly scheduled hours in which tests are performed.** Technical Supervisor spends an adequate amount of time in the laboratory supervising the technical performance of the staff and is readily available for consultation. The Technical Supervisor position has a minimum education requirement of a master's degree for some specialties/subspecialties.

Pages 3-5:

14. Laboratory Tests Performed- Instructions found on page 3. Laboratory workload data (pages 3-5): The annual numbers of tests or specimens must be entered. Refer to "Guidelines for Counting Tests for CLIS-Laboratory Workload Data" below.

For a listing of FDA-approved analyte specialties, refer to <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>.

Enrollment in proficiency testing – Please indicate on page 5, your proficiency testing provider(s), e.g., CAP, AAB.

For a listing of CMS-Approved Proficiency Testing Programs, refer to: <http://www.cms.gov/CLIA/downloads/ptlist.pdf>

Page 6:

15. Referred Work

16. Equipment - List all current equipment in use for 2012. Do not rely on what was submitted in prior applications.

17. Physical Plant- For Initial applicants only.

18. Laboratory Charges – Please submit Fee Schedules on CD-Rom.

19. Certification: **the director and owners must sign the application.** Notarization is no longer required.

Page 7:

20. Licensure fees: Please also include a photocopy of your check submitted for all fees. Include CLIS ID Number on the check and attach check to the application.

GUIDELINES FOR COUNTING TESTS FOR CLIS LABORATORY WORKLOAD DATA

- For **histocompatibility**, each HLA typing (including disease associated antigens), HLA cross match is counted as one test.
- For **microbiology**, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per specimen regardless of the extent of identification, number of organisms isolated and number of test/procedures required for identification.
- Testing for allergens should be counted as one test per individual allergen.
- For **chemistry** profiles, each individual analyte is counted separately.
- For **urinalysis**, microscopic and macroscopic examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.
- For **complete blood counts**, each measured individual analyte that is ordered and reported is counted separately. Differentials are counted as one test.
- Do not count calculations (e.g., A/G ratio, MCH, and T7), quality control, quality assurance and proficiency testing assays.
- For **immunohematology**, each ABO, Rh, antibody screen, cross match or antibody identification is counted as one test.
- For **cytology**, each slide (not case) is counted as one test for both Pap smears and nongynecologic cytology.
- For **cytogenetics**, the number of tests is determined by the number of specimen types processed on each patient, e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests.

Collection Stations

Collection stations have a new application form CL-18. For collection stations, indicate the actual address of the collection station. Each collection station has a unique CLIS ID. Please list this on the CL-18 and any correspondence to the CLIS Licensing Unit. Please be sure to include the name and address of the parent laboratory.

Test Expansion/Prelicensure

Licensure in a specialty does not allow you to add tests or subspecialties under that specialty without approval from CLIS. For example, licensure in Toxicology for therapeutic drug monitoring does not permit you to perform testing for drugs of abuse. If you intend to offer an additional test or examination in 2012, a written request, signed by the laboratory director, must be submitted for the addition. You must demonstrate that you have successfully participated in an approved proficiency-testing program for at least one event (minimum four challenges), before we will approve it for patient testing and add it to your license. If an approved proficiency-testing program is not available, acceptable documentation of validation must be submitted with your expansion request.

Notification of Changes

You are reminded that under the provisions of N.J.S.A. 45:9-42.32, you must notify the Clinical Laboratory Improvement Services (CLIS) in writing within 14 calendar days when a change in ownership or directorship occurs. A laboratory that changes ownership is required to re-apply for licensure that includes submitting the completed form CL-3.

You must also notify CLIS when there are changes in the operation of the laboratory, such as termination of services, address, hours of operation, supervisory personnel and any additions or deletions to your testing menu. Any changes must be submitted in writing and signed by the laboratory director.

Out-of-State Laboratories

Please note that laboratories located outside the State of New Jersey will be required to obtain a clinical laboratory license for 2012, only if that out-of-state laboratory has a collection station in the State of New Jersey or is directly involved in the collection or transport of specimens from New Jersey facilities to the out-of-state laboratory.

N.J.S.A. 45:9-4 2.27.a. defines a collection station as “any facility used for the collection, processing and transmission of specimens to another facility for the performance of clinical tests.”

Mailing Address/Written Correspondence

Please enclose a return mailing label or envelope with all applications for accurate delivery of your 2012 license.

With the exception of the completed Excel spreadsheet for Laboratory Personnel Information that is to be e-mailed to clislicensing@njlicns.net the license application and all requested attachments shall be mailed to:

Regular Mail

Joan Mikita, Licensing Unit
Clinical Laboratory Improvement Services
New Jersey Department of Health and Senior Services
P.O. Box 361
Trenton, NJ 08625-0361

Next day or 2nd Day Air

Joan Mikita, Licensing Unit
Clinical Laboratory Improvement Services
New Jersey Department of Health and Senior Services
Public Health and Environmental Laboratories
3 Schwarzkopf Drive
Ewing, NJ 08628

If you have any questions or require assistance, you may contact the Licensing and Regulatory Compliance Unit at 609-406-6830.

**Joan Mikita, M.S., Supervisor
Licensing, Proficiency Testing and Regulatory Compliance
Clinical Laboratory Improvement Services**

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

(13) LABORATORY PERSONNEL INFORMATION

PLEASE READ THE FOLLOWING BEFORE ENTERING LABORATORY PERSONNEL INFORMATION!

NOTE: When providing the requested information for laboratory personnel, it is preferred that laboratories complete the Laboratory Personnel Excel spreadsheet by clicking on the corresponding link at our website.

Complete the spreadsheet electronically, and e-mail it to clislicensing@njlinics.net.

If you do not have the capability to complete the spreadsheet electronically, please complete the Laboratory Personnel Information section on this page of the license application.

List all personnel who are serving as a director, co-director, general supervisor, technical supervisor, clinical consultant, cytology general supervisor, technologist, cytotechnologist, technician, trainee, technical aide, or phlebotomist in the laboratory. Use the codes below to indicate the function of each employee. Attach additional pages if necessary.

NAME (Last, First, Middle Initial)	Degree	Time			Function As:										FOR STATE USE ONLY			
		Full Time	Part Time	P/T Hrs./ Day	D/ CO	GS	TS	CC	CT/ GS	T	CT	TN	A	P				

Codes:	TS - Technical Supervisor	T - Technologist	
D/CO - Director/Co-Director	CC - Clinical Consultant	CT - Cytotechnologist	A - Laboratory Assistant
GS - General Supervisor	CT/GS - Cytology General Supervisor	TN - Technician	P - Phlebotomist Only

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

(14) LABORATORY TESTS PERFORMED

Place a check (X) by any test performed at your clinical laboratory site. If test(s) you perform are not listed, enter them under the appropriate specialty/subspecialty. For test volumes, include the YEARLY estimate of the number of tests performed within each specialty/subspecialty.

New Jersey Licensed Clinical Laboratories MUST participate in a CMS-approved Proficiency Testing (PT) Program for each **bolded** Analyte/Test listed below and shall have the PT Program forward survey results to NJDHSS/CLIS for review. If the test is CLIA waived, please place a check (X) in the CLIA-waived column.

Laboratories shall participate in PT surveys for the bolded Analytes/Tests listed, which consist of five (5) challenges per survey and three (3) surveys per year, except as follows:

Laboratories performing testing for the **bolded** Analytes/Tests listed below, using CLIA waived test kits or instruments, may participate in PT surveys providing a minimum of two (2) challenges per survey and two (2) surveys per year, except that five (5) challenge PT surveys shall be performed for Prothrombin Time/INR, HIV, Blood Lead and other future CLIA tests classified as waived, which may be designated by CLIS as requiring participation in five (5) challenge PT surveys. The Department may require a laboratory with unsatisfactory performance in PT surveys for waived tests to participate in five (5) challenge surveys for that waived test or tests.

For non-bolded Analytes/Tests, laboratories shall participate in proficiency testing, if available, or shall verify test system accuracy at least twice yearly.

X	Specialty / Subspecialty	No. of Tests Performed Annually	Check (X) if CLIA Waived	X	Specialty / Subspecialty	No. of Tests Performed Annually	Check (X) if CLIA Waived
	URINALYSIS		/////		MYCOLOGY		/////
	Reagent Strip (NJ Waived)	/////			Class I Initiation and/or Screen Only	/////	
	Reagent Strip Automated	/////			Class II Initiation of Cultures Only	/////	
	Microscopic	/////			Class III Complete ID of Yeast Only	/////	
	Urine Pregnancy (NJ Waived)	/////			Class IV Complete ID, Other than Yeast	/////	
	BACTERIOLOGY/MICROSCOPIC PROCEDURES		/////		KOH (Skin, Hair and Nails)	/////	
	Antibiotic Sensitivities	/////			DTM Only	/////	
	Bacterial Antigens	/////				/////	
	Clostridium difficile	/////				/////	
	Group A Strep (Rapid Test)	/////				/////	
	Group B Strep	/////				/////	
	Blood Culture	/////			ROUTINE CHEMISTRY		/////
	Chlamydia	/////			ALT/SGPT	/////	
	CSF Culture	/////			Albumin	/////	
	Gram Stain	/////			Alkaline Phosphatase	/////	
	Legionella pneumophila Antigen Detection	/////			Amylase	/////	
	Gardnerella vaginalis	/////			AST/SGOT	/////	
	N. gonorrhoeae Culture	/////			Bilirubin, Total/Neonatal	/////	
	N. gonorrhoeae/DNA Probe	/////			pH (Blood Gas)	/////	
	Throat Culture	/////			pO ₂ (Blood Gas)	/////	
	Urine Culture	/////			pCO ₂ (Blood Gas)	/////	
	Urine Colony Count	/////			Calcium	/////	
	Other Culture/ID: _____	/////			Carbon Dioxide	/////	
	Vaginal Wet Mounts (KOH Prep)	/////			Chloride	/////	
	Yeast Screen (not definitive, e.g., germ tube)	/////			Cholesterol, Total	/////	
	Fecal leukocytes	/////			HDL Cholesterol	/////	
	Fern tests	/////			Creatine Kinase	/////	
	Nasal Smear for Granulocytes	/////			CK Isoenzymes	/////	
		/////			Creatinine	/////	
	MYCOBACTERIOLOGY		/////		Glucose, Serum or Plasma	/////	
	Class I AFB Smears Only	/////			Glucose, Whole Blood (NJ Waived)	/////	
	Class II AFB Smears and Initiation of Culture	/////			Glycohemoglobin (Hgb A1C or equivalent)	/////	
	Class III Complete ID of TB Complex Only	/////			Iron, Total	/////	
	Class IV Complete ID of Other Species	/////			LDH	/////	
		/////			LDH Isoenzymes	/////	
		/////			Magnesium	/////	
		/////			Potassium	/////	
		/////			PSA	/////	
		/////			Sodium	/////	
		/////			Total Protein	/////	
		/////			Triglycerides	/////	

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

LABORATORY TESTS PERFORMED, Continued							
X	Specialty / Subspecialty	No. of Tests Performed Annually	Check (X) if CLIA Waived	X	Specialty / Subspecialty	No. of Tests Performed Annually	Check (X) if CLIA Waived
	ROUTINE CHEMISTRY, Continued	//////	//////		ENDOCRINOLOGY		//////
	Urea Nitrogen (BUN)	//////			Cortisol	//////	
	Uric Acid	//////			Free Thyroxine	//////	
	CEA	//////			HCG (Serum Pregnancy or Non-Waived Urine HCG)	//////	
	Cholinesterase	//////			T3 or T Uptake	//////	
	CRP/HSCR	//////			Triiodothyronine (T3)	//////	
	Ferritin	//////			TSH	//////	
	GGT	//////			Thyroxine (T4)	//////	
	Phosphorus	//////			Estradiol	//////	
	Myoglobin	//////			FSH	//////	
	Troponin	//////			Luteinizing Hormone	//////	
	BNP	//////			Progesterone	//////	
	Protein Electrophoresis	//////			Testosterone	//////	
		//////				//////	
		//////				//////	
	PARASITOLOGY		//////			//////	
	Blood Parasite	//////				//////	
	Fecal Suspension (Wet Mount)	//////			TOXICOLOGY		//////
	Fecal Suspension (Giardia and/or Cryptosporidium Immunoassay)	//////			Blood Alcohol	//////	
	Giemsa-stained Blood Smear	//////			Blood Lead	//////	
	Parasite Identification	//////			Carbamazepine	//////	
	Tissue Parasite Identification	//////			Digoxin	//////	
	PVA Slide	//////			Ethosuximide	//////	
		//////			Gentamicin	//////	
		//////			Lithium	//////	
	VIROLOGY *		//////		Phenobarbital	//////	
	Adenovirus Antigen	//////			Phenytoin	//////	
	C. trachomatis (EIA) Antigen Detection	//////			Primidone	//////	
	C. trachomatis (IF) Antigen Detection	//////			Procainamide/Metabolites	//////	
	C. trachomatis/DNA Probe	//////			Quinidine	//////	
	Cytomegalovirus (CMV)	//////			Theophylline	//////	
	Enterovirus	//////			Tobramycin	//////	
	Herpes Simplex Virus (Antigen Detection)	//////			Valproic Acid	//////	
	Herpes Simplex Virus Culture	//////			Drugs of Abuse (Urine)	//////	
	Influenza Viruses	//////			Urine Alcohol	//////	
	Parainfluenza Type 2 Antigen	//////			Erythrocyte Porphyrin (EP)	//////	
	Parainfluenza Viruses	//////				//////	
	Rotavirus Antigen	//////			IMMUNOHEMATOLOGY		//////
	RSV	//////			Antibody Detection (Unexpected)	//////	
	Varicella-Zoster Virus	//////			ABO Group	//////	
	Viral Antigen Detection	//////			D (Rh) Typing	//////	
	Viral Isolation/Identification	//////			Antibody Identification	//////	
	Human Papillomavirus (HPV)	//////			Compatibility Test (Crossmatch)	//////	
	Rapid Flu	//////				//////	
		//////				//////	
		//////				//////	

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

LABORATORY TESTS PERFORMED, Continued							
X	Specialty / Subspecialty	No. of Tests Performed Annually	Check (X) if CLIA Waived	X	Specialty / Subspecialty	No. of Tests Performed Annually	Check (X) if CLIA Waived
	GENERAL IMMUNOLOGY		/////		HEMATOLOGY/COAGULATION, Continued	/////	/////
	<i>Allergy Testing</i>	/////			QBC Hematology	/////	
	Alpha-1 Antitrypsin	/////			<i>Reticulocyte Count</i>	/////	
	AFP/Tumor Markers	/////			<i>Hemoglobin Electrophoresis</i>	/////	
	<i>AFP/Other</i>	/////			<i>Semen Analysis/Count</i>	/////	
	ANA	/////			<i>Fecal Occult Blood (NJ Waived)</i>	/////	
	ASO	/////			<i>ESR (Non-automated, NJ Waived)</i>	/////	
	HIV	/////			<i>ESR (Automated)</i>	/////	
	C3	/////			<i>Hemoglobin (NJ Waived)</i>	/////	
	C4	/////			Fibrinogen	/////	
	Hepatitis A Virus Antibody	/////			PTT	/////	
	Hepatitis B Core Antibody	/////			Prothrombin Time	/////	
	Hepatitis B Core Antigen	/////			INR	/////	
	Hepatitis B Surface Antibody	/////			<i>Thrombin Time</i>	/////	
	Hepatitis B Surface Antigen	/////			<i>Factor Assays</i>	/////	
	Hepatitis C	/////			<i>Activated Clotting Time</i>	/////	
	Hepatitis C Virus Antibody	/////			<i>D-dimer</i>	/////	
	Hepatitis Be Antigen	/////				/////	
	IgA	/////				/////	
	IgG	/////				/////	
	IgE	/////			CYTOLOGY/HISTOLOGY		/////
	IgM	/////			GYN	/////	
	Infectious Mononucleosis	/////			<i>Non GYN</i>	/////	
	Rheumatoid Factor	/////			<i>Urine</i>	/////	
	<i>H. pylori</i>	/////			<i>Histology Processing</i>	/////	
	Rubella Antibody	/////				/////	
	<i>Flow Cytometry</i>	/////				/////	
		/////				/////	
		/////			GENETICS AND/OR TISSUE TYPING		/////
	SYPHILIS SEROLOGY		/////		<i>Biochemical Genetic Tests (List Tests)</i>	/////	
	RPR	/////				/////	
	VDRL	/////				/////	
	MHA-TP (TP-PA)	/////				/////	
	FTA	/////				/////	
		/////			<i>Cytogenetic Tests (List Tests)</i>	/////	
		/////				/////	
	HEMATOLOGY/COAGULATION		/////			/////	
	Cell Identification/Manual Differential	/////				/////	
	CBC (Complete Blood Count)	/////				/////	
	Automated WBC Differential	/////			<i>Molecular Genetic Tests (List Tests) (Add HPV Testing under Virology)</i>	/////	
	RBC	/////				/////	
	Hematocrit (excluding Spun Microhematocrit)	/////				/////	
	Hemoglobin (excluding Copper Sulfate)	/////				/////	
	WBC	/////			Total Number of Tests Performed Annually – All Categories		
	Platelet Count	/////					

CURRENT PROFICIENCY TESTING PROVIDER	
Calendar Year	Name of Proficiency Testing Provider

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

(15) REFERRED WORK

Do you refer work to other laboratories? Yes No

If Yes, provide the names and addresses of laboratories to which you refer work. (Attach additional page if necessary).

(16) EQUIPMENT

Include, by attachment, a list of all major equipment now in use, including makes, models or types, sizes or capacity, age and current condition. Include microbiological safety cabinets, giving name of manufacturer and model.

(17) PHYSICAL PLANT

For Initial Applications, include, by attachment, a description and plan of the premises to be occupied for the laboratory's operation.

(18) LABORATORY CHARGES

Please provide on a CD-ROM if possible, or provide hard copy of all current fee schedules.

(19) CERTIFICATION

We the undersigned certify that all the information given on this application and on the accompanying attachments is true, correct and complete as of this date and that notification, by certified mail, of any change(s) will be made within 14 days of such change(s).

We further certify that testing will not be performed until all applicable State and Federal certificates, licenses and required approvals have been obtained in accordance with N.J.S.A. 45:9-42 et seq., N.J.A.C. 8:44 and 42 CFR 493.1 et seq., and applicable approved CLSI standards and guidelines.

We attest that we have have not been indicted for or convicted of a felony crime and that the owner(s) and laboratory director are not presently suspended or had a CLIA certificate revoked and are not subject to pending administrative sanctions under any Federal, State or local laws. (**Attach complete documentation regarding conviction, suspension, revocation or administrative actions.**)

Please number all attachments consecutively and record the number of pages attached to this application.

Number of pages attached:

Signature of Director	Date
Signature of Owner	Date
Signature of Owner	Date
Signature of Owner	Date

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

(20) LICENSURE FEES

Initial license application fees and annual license renewal fees are identical. Fees noted are for each specialty. Complete and return this page with your application.

Calculating Total Number of Employees of Entire Laboratory (or use your established system for calculation):

- A. Number of Full-Time Employees _____
- B. Total Number of Hours of Part-Time Laboratory Employees per Week _____
- C. Part Time Employee Hours Pro-Rated to Full Time = (B) ÷ 40 = (D)
(Round to the nearest whole number) _____
- D. Total Number of Employees [(A) + (C) = (D)] _____

Staff Category / Fee Per Specialty

[Check category based on the Total Number of Employees of Entire Laboratory (from "D" above)]

[Do not include director, co-director, students of approved schools of medical technology, clerical and maintenance employees. Part-time employees are to be included, pro-rated to full-time equivalents.]

<input type="checkbox"/> Category I 1-9 Employees \$200	<input type="checkbox"/> Category II 10-29 Employees \$250	<input type="checkbox"/> Category III 30-49 Employees \$300	<input type="checkbox"/> Category IV 50-89 Employees \$350	<input type="checkbox"/> Category V 90 or More Employees \$400
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Specialty(ies) Offered by Laboratory (Check only NJ non-waived test specialties)

- | | | |
|---|--|--|
| <input type="checkbox"/> Urinalysis | <input type="checkbox"/> Virology | <input type="checkbox"/> Routine Chemistry |
| <input type="checkbox"/> Bacteriology | <input type="checkbox"/> Diagnostic Immunology (includes General Immunology and Syphilis Serology) | <input type="checkbox"/> Endocrinology |
| <input type="checkbox"/> Mycobacteriology | <input type="checkbox"/> Hematology/Coagulation | <input type="checkbox"/> Toxicology |
| <input type="checkbox"/> Parasitology | <input type="checkbox"/> Immunohematology | <input type="checkbox"/> Cytology/Histology |
| <input type="checkbox"/> Mycology | | <input type="checkbox"/> Cytogenetics and/or Tissue Typing |

Total Number of NJ Non-Waived Specialties Checked: _____

LATE FEE:

Laboratories submitting renewal applications after December 31st are required to pay an additional late fee of \$100.

NOTE:

Laboratories requiring a replacement license due to a change of name or address must submit a \$100 fee per change.

FEE CALCULATION:

(Include CLIS ID Number on check. Include photocopy of submitted check. Attach check to application.)

- | | | |
|----|--|-----------------|
| 1. | Total Number of Employees of Entire Laboratory (as calculated above) | _____ |
| 2. | Category Based on Total Number of Employees of Entire Laboratory | _____ |
| 3. | Fee Per Specialty as Indicated under the Appropriate Category | \$ _____ |
| 4. | Number of Licensed Specialties | _____ |
| 5. | Total Licensure Fee
[Fee Per Specialty Multiplied by Number of Licensed Specialties (Line 3 x Line 4)]..... | \$ _____ |
| 6. | Late Fee of \$100.00 (if applicable)
<i>(for <u>renewal</u> applications submitted after December 31)</i> | \$ _____ |
| 7. | Total Fee [Licensure Fee (Line 5) + Late Fee (Line 6) (if applicable)] | \$ _____ |