

(2) Type of Application

Initial Renewal

FOR STATE USE ONLY:	Date Received	Received By	<input type="checkbox"/> Approved
	Check Number	Amount	Check Date

(3) Name of Laboratory		(7) Name of Parent Lab and CLIS ID Number (if applicable)	
Street Address		Street Address	
City, State, Zip Code		City, State, Zip Code	
(4) CLIS ID Number	(5) CLIA Number	(8) Normal Hours of Laboratory Operation [Indicate specific hours <u>EACH</u> day]:	
(6) Name of Contact Person and Phone Number			
Telephone Number of Laboratory ()			
Fax Number of Laboratory ()			
Email Address of Contact Person			
Monday _____		Tuesday _____	
Wednesday _____		Thursday _____	
Friday _____		Saturday _____	
Sunday _____			

(9) Type of Laboratory (Check only one appropriate type)

<input type="checkbox"/> Hospital	<input type="checkbox"/> Ambulatory Surgical Center	<input type="checkbox"/> School
<input type="checkbox"/> Hospital Associated (Off Site)	<input type="checkbox"/> Industrial Medicine Department/ Employee Health Offices	<input type="checkbox"/> Urgent Care Services
<input type="checkbox"/> Independent	<input type="checkbox"/> Mobile Testing	<input type="checkbox"/> Other: _____
<input type="checkbox"/> Physician Office		

(10) CLIA Certificate: Type of certificate that the Laboratory has or for which the Laboratory has applied:

Certificate of Waiver Certificate for Provider Performed Microscopy Procedures Certificate of Compliance

Certificate of Accreditation: Accrediting Agency: CAP COLA TJC Other: _____

(11) OWNERSHIP INFORMATION (Attach CL-9 Form)

Name of Owner/Authorized Agent	Telephone Number ()
Home Address	Type of Ownership
City, State, Zip Code	<input type="checkbox"/> Individual <input type="checkbox"/> Government-Type: <input type="checkbox"/> Partnership <input type="checkbox"/> State <input type="checkbox"/> Corporation <input type="checkbox"/> County <input type="checkbox"/> Non-Profit <input type="checkbox"/> Municipal

Complete and submit the Disclosure of Ownership and Control Interest form (CL-9). List all individuals having direct or indirect ownership or a controlling interest. Form CL-9 is available at www.nj.gov/health/phel/clinical-lab-imp-services/.

(12) INFORMATION ON LABORATORY DIRECTOR

Name of Laboratory Director	Telephone Number ()
Home Address	
Is Director licensed as a Bioanalytical Laboratory Director in New Jersey? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, give Bioanalytical Laboratory Director's License No.: _____ Expiration Date: _____	
Director's Qualifications: <input type="checkbox"/> Pathologist <input type="checkbox"/> MD <input type="checkbox"/> DDS <input type="checkbox"/> Ph.D. <input type="checkbox"/> Masters	
<input type="checkbox"/> CP <input type="checkbox"/> AP <input type="checkbox"/> DO <input type="checkbox"/> DVM <input type="checkbox"/> D.Sc. <input type="checkbox"/> Bachelor	
Director's Time on Premises (Indicate specific hours each day, e.g., 1:30 PM - 3:00 PM):	
Mon _____	Tue _____
Fri _____	Sat _____
	Sun _____
	Thu _____

Does Director serve as Director or Co-Director for laboratories at other locations? Yes No

If yes, list the names and addresses of the other laboratories, whether or not located in New Jersey:

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, laboratories may complete the Laboratory Personnel Excel spreadsheet found at <http://www.state.nj.us/health/phel/documents/labworkforce.xls>.

Complete the spreadsheet electronically, **and mail it with your CL-3.**

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, 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	CT/ GS	T	CT	TN	A		P	

Codes:

D/CO - Director/Co-Director	CT/GS - Cytology General Supervisor	TN - Technician
GS - General Supervisor	T - Technologist	A - Laboratory Assistant
TS - Technical Supervisor	CT - Cytotechnologist	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 NJDOH/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. 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		/////
	Microscopic	/////			Class I Initiation and/or Screen Only	/////	
	Reagent Strip (NJ Waived)	/////			Class II Initiation of Cultures Only	/////	
	Reagent Strip Automated	/////			Class III Complete ID of Yeast Only	/////	
	Urine Pregnancy (NJ Waived)	/////			Class IV Complete ID, Other than Yeast	/////	
	BACTERIOLOGY		/////		DTM Only	/////	
	Antibiotic Sensitivities	/////			KOH (Skin, Hair and Nails)	/////	
	Bacterial Antigens	/////				/////	
	Clostridium difficile	/////			CHEMISTRY		/////
	Group A Strep (Rapid Test)	/////			Albumin	/////	
	Group B Strep	/////			Alkaline Phosphatase	/////	
	Blood Culture	/////			ALT/SGPT	/////	
	Chlamydia	/////			Amylase	/////	
	CSF Culture	/////			AST/SGOT	/////	
	Fern tests	/////			Bilirubin, Total/Neonatal	/////	
	Gardnerella vaginalis	/////			BNP	/////	
	Gram Stain	/////			Calcium	/////	
	Legionella pneumophila Antigen Detection	/////			Carbon Dioxide	/////	
	N. gonorrhoeae Culture	/////			CEA	/////	
	N. gonorrhoeae/DNA Probe	/////			Chloride	/////	
	Throat Culture	/////			Cholesterol, Total	/////	
	Urine Culture	/////			Cholinesterase	/////	
	Urine Colony Count	/////			CK Isoenzymes	/////	
	Other Culture/ID: _____	/////			Creatine Kinase	/////	
	Vaginal Wet Mounts (KOH Prep)	/////			Creatinine	/////	
	Yeast Screen (not definitive, e.g., germ tube)	/////			CRP/HSCRp	/////	
		/////			Ferritin	/////	
		/////			GGT	/////	
	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	/////			HDL Cholesterol	/////	
	Class IV Complete ID of Other Species	/////			Iron, Total	/////	
		/////			LDH	/////	
		/////			LDH Isoenzymes	/////	

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
	CHEMISTRY, Continued	//////	//////		ENDOCRINOLOGY		//////
	Magnesium	//////			Cortisol	//////	
	Myoglobin	//////			Estradiol	//////	
	pCO ₂ (Blood Gas)	//////			Free Thyroxine	//////	
	pH (Blood Gas)	//////			FSH	//////	
	Phosphorus	//////			HCG (Serum Pregnancy or Non-Waived Urine HCG)	//////	
	pO ₂ (Blood Gas)	//////			Luteinizing Hormone	//////	
	Potassium	//////			Progesterone	//////	
	Protein Electrophoresis	//////			T3 or T Uptake	//////	
	PSA	//////			Testosterone	//////	
	Sodium	//////			Triiodothyronine (T3)	//////	
	Total Protein	//////			TSH	//////	
	Triglycerides	//////			Thyroxine (T4)	//////	
	Troponin	//////				//////	
	Urea Nitrogen (BUN)	//////				//////	
	Uric Acid	//////				//////	
		//////				//////	
		//////			TOXICOLOGY/TDM		//////
		//////			Blood Alcohol	//////	
	PARASITOLOGY		//////		Blood Lead	//////	
	Blood Parasite	//////			Carbamazepine	//////	
	Fecal Suspension (Wet Mount)	//////			Digoxin	//////	
	Fecal Suspension (Giardia and/or Cryptosporidium Immunoassay)	//////			Drugs of Abuse Confirmatory	//////	
	Giemsa-stained Blood Smear	//////			Drugs of Abuse Screen	//////	
	Parasite Identification	//////			Ethosuximide	//////	
	Tissue Parasite Identification	//////			Gentamicin	//////	
		//////			Lithium	//////	
		//////			Phenobarbital	//////	
		//////			Phenytoin	//////	
	VIROLOGY		//////		Primidone	//////	
	Adenovirus Antigen	//////			Procainamide/Metabolites	//////	
	Cytomegalovirus (CMV)	//////			Quinidine	//////	
	Enterovirus	//////			Theophylline	//////	
	Herpes Simplex Virus (Antigen Detection)	//////			Tobramycin	//////	
	Herpes Simplex Virus Culture	//////			Urine Alcohol	//////	
	Human Papillomavirus (HPV)	//////			Valproic Acid	//////	
	Influenza Viruses	//////				//////	
	Parainfluenza Type 2 Antigen	//////				//////	
	Parainfluenza Viruses	//////				//////	
	Rapid Flu	//////			IMMUNOHEMATOLOGY		//////
	Rotavirus Antigen	//////			ABO Group	//////	
	RSV	//////			Antibody Detection (Unexpected)	//////	
	Varicella-Zoster Virus	//////			Antibody Identification	//////	
	Viral Antigen Detection	//////			Compatibility Test (Crossmatch)	//////	
	Viral Isolation/Identification	//////			D (Rh) Typing	//////	
		//////				//////	
		//////				//////	
		//////				//////	

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
	DIAGNOSTIC IMMUNOLOGY		/////		HEMATOLOGY, Continued	/////	/////
	<i>AFP/Other</i>	/////			WBC	/////	
	AFP/Tumor Markers	/////			Platelet Count	/////	
	<i>Allergy Testing</i>	/////			Cell Identification/Manual Differential	/////	
	Alpha-1 Antitrypsin	/////			<i>D-dimer</i>	/////	
	ANA	/////			<i>ESR (Automated)</i>	/////	
	ASO	/////			<i>ESR (Non-automated, NJ Waived)</i>	/////	
	C3	/////			<i>Factor Assays</i>	/////	
	C4	/////			<i>Fecal Occult Blood (NJ Waived)</i>	/////	
	<i>Flow Cytometry</i>	/////			Fibrinogen	/////	
	H. pylori	/////			INR	/////	
	<i>Hepatitis A Virus Antibody</i>	/////			Prothrombin Time	/////	
	<i>Hepatitis B Core Antibody</i>	/////			PTT	/////	
	Hepatitis B Core Antigen	/////			QBC Hematology	/////	
	<i>Hepatitis B Surface Antibody</i>	/////			<i>Reticulocyte Count</i>	/////	
	Hepatitis B Surface Antigen	/////			<i>Semen Analysis/Count</i>	/////	
	Hepatitis Be Antigen	/////			<i>Thrombin Time</i>	/////	
	<i>Hepatitis C</i>	/////				/////	
	<i>Hepatitis C Virus Antibody</i>	/////				/////	
	HIV	/////				/////	
	IgA	/////				/////	
	IgE	/////			CYTOLOGY		/////
	IgG	/////			GYN	/////	
	IgM	/////			<i>Non GYN</i>	/////	
	Infectious Mononucleosis	/////			<i>Urine</i>	/////	
	Rheumatoid Factor	/////				/////	
	Rubella Antibody	/////				/////	
		/////				/////	
		/////			GENETICS AND/OR TISSUE TYPING		/////
	SYPHILIS SEROLOGY		/////		<i>Biochemical Genetic Tests (List Tests)</i>	/////	
	FTA	/////				/////	
	MHA-TP (TP-PA)	/////				/////	
	RPR	/////				/////	
	VDRL	/////				/////	
		/////			<i>Cytogenetic Tests (List Tests)</i>	/////	
		/////				/////	
	HEMATOLOGY		/////			/////	
	<i>Activated Clotting Time</i>	/////				/////	
	CBC (Complete Blood Count)	/////			<i>Molecular Genetic Tests (List Tests) (Add HPV Testing under Virology)</i>	/////	
	Automated WBC Differential	/////				/////	
	RBC	/////				/////	
	Hematocrit (excluding Spun Microhematocrit)	/////				/////	
	Hemoglobin (excluding Copper Sulfate)	/////			Total Number of Tests Performed Annually – All Categories		

CURRENT PROFICIENCY TESTING PROVIDER(S)	
Calendar Year	Name of Proficiency Testing Provider(s)

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 plan of the premises or a photograph of the area to be occupied for the laboratory's operation.

(18) 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. 45:9-42.26 et seq., N.J.A.C. 8:44-2.1 et seq. and 42 CFR 493.1 et seq.

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

(19) LICENSURE FEES FOR LABORATORIES PERFORMING ANY CLIA NON-WAIVED TESTS

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, phlebotomists 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
----------------------------------------------------------------------	-------------------------------------------------------------------------	--------------------------------------------------------------------------	-------------------------------------------------------------------------	-----------------------------------------------------------------------------

Specialty(ies) Offered by Laboratory

- | | | |
|-------------------------------------------|----------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| <input type="checkbox"/> Urinalysis | <input type="checkbox"/> Diagnostic Immunology (includes General Immunology and Syphilis Serology) | <input type="checkbox"/> Toxicology/TDM |
| <input type="checkbox"/> Bacteriology | <input type="checkbox"/> Hematology | <input type="checkbox"/> Cytology |
| <input type="checkbox"/> Mycobacteriology | <input type="checkbox"/> Immunohematology | <input type="checkbox"/> Genetics and/or Tissue Typing |
| <input type="checkbox"/> Parasitology | <input type="checkbox"/> Chemistry | <input type="checkbox"/> CLIA Waived (\$200.00) |
| <input type="checkbox"/> Mycology | <input type="checkbox"/> Endocrinology | |
| <input type="checkbox"/> Virology | | |

Total Number of CLIA 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 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. CLIA Waived Fee of \$200.00 (if applicable) **\$** _____
- 7. Late Fee of \$100.00 (if applicable)
(for renewal applications submitted after December 31)..... **\$** _____
- 8. Total Fee [Licensure Fee (Line 5) + CLIA Waived Fee of \$200.00 (Line 6) (if applicable)
+ Late Fee (Line 7) (if applicable)] **\$** _____