New Jersey Department of Health
Clinical Laboratory Improvement Services
PO Box 361
Trenton, NJ 08625-0361

APPLICATION FOR A CLINICAL LABORATORY LICENSE
CLIA NON-WAIVED TESTS / ONSITE TESTING ONLY
(1) CY _____

(2) Type of Application			
☐ Initial ☐ Renewal	**FOR STATE USE ONLY:** Date Received	Received By	☐ 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 EACH day]:
(6) Name of Contact Person and Phone Number	Monday _____
Telephone Number of Laboratory ( )	Tuesday _____
Fax Number of Laboratory ( )	Wednesday _____
Email Address of Contact Person	Thursday _____
	Friday _____
	Saturday _____
	Sunday _____

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

☐ Hospital
☐ Hospital Associated (Off Site)
☐ Independent
☐ Physician Office
☐ Ambulatory Surgical Center
☐ Industrial Medicine Department/ Employee Health Offices
☐ Mobile Testing
☐ School
☐ Urgent Care Services
☐ Other: _____

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

☐ 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: ☐ Individual ☐ Partnership ☐ Corporation ☐ Non-Profit ☐ Government-Type: ☐ State ☐ County ☐ Municipal
City, State, Zip Code	

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? ☐ Yes ☐ No

If yes, give Bioanalytical Laboratory Director's License No.: _____ Expiration Date: _____

Director's Qualifications: ☐ Pathologist ☐ CP ☐ AP ☐ MD ☐ DO ☐ DDS ☐ D.Sc. ☐ Ph.D. ☐ Bachelor ☐ Masters

Director's Time on Premises (Indicate specific hours each day, e.g., 1:30 PM - 3:00 PM):

Mon _____ Tue _____ Wed _____ Thu _____
Fri _____ Sat _____ Sun _____

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 <u>BEFORE</u> 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
GS - General Supervisor
TS - Technical Supervisor
CT/GS - Cytology General Supervisor
T - Technologist
CT - Cytotechnologist
TN - Technician
A - Laboratory Assistant
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.

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
URINALYSIS			//////
	Microscopic	//////	
	Reagent Strip	//////	
	Reagent Strip Automated	//////	
	Urine Pregnancy	//////	
BACTERIOLOGY			//////
	Antibiotic Sensitivities	//////	
	Bacterial Antigens	//////	
	Clostridium difficile	//////	
	Group A Strep (Rapid Test)	//////	
	Group B Strep	//////	
	Blood Culture	//////	
	Chlamydia	//////	
	CSF Culture	//////	
	Fern tests	//////	
	Gardnerella vaginalis	//////	
	Gram Stain	//////	
	Legionella pneumophila Antigen Detection	//////	
	N. gonorrhoeae Culture	//////	
	N. gonorrhoeae/DNA Probe	//////	
	Throat Culture	//////	
	Urine Culture	//////	
	Urine Colony Count	//////	
	Other Culture/ID: _____	//////	
	Vaginal Wet Mounts (KOH Prep)	//////	
	Yeast Screen (not definitive, e.g., germ tube)	//////	
		//////	
		//////	
MYCOBACTERIOLOGY			//////
	Class I AFB Smears Only	//////	
	Class II AFB Smears and Initiation of Culture	//////	
	Class III Complete ID of TB Complex Only	//////	
	Class IV Complete ID of Other Species	//////	
		//////	
		//////	

X	Specialty / Subspecialty	No. of Tests Performed Annually	Check (X) if CLIA Waived
MYCOLOGY			//////
	Class I Initiation and/or Screen Only	//////	
	Class II Initiation of Cultures Only	//////	
	Class III Complete ID of Yeast Only	//////	
	Class IV Complete ID, Other than Yeast	//////	
	DTM Only	//////	
	KOH (Skin, Hair and Nails)	//////	
		//////	
		//////	
CHEMISTRY			//////
	Albumin	//////	
	Alkaline Phosphatase	//////	
	ALT/SGPT	//////	
	Amylase	//////	
	AST/SGOT	//////	
	Bilirubin, Total/Neonatal	//////	
	BNP	//////	
	Calcium	//////	
	Carbon Dioxide	//////	
	CEA	//////	
	Chloride	//////	
	Cholesterol, Total	//////	
	Cholinesterase	//////	
	CK Isoenzymes	//////	
	Creatine Kinase	//////	
	Creatinine	//////	
	CRP/HSCRP	//////	
	Ferritin	//////	
	GGT	//////	
	Glucose, Serum or Plasma	//////	
	Glucose, Whole Blood	//////	
	Glycohemoglobin (Hgb A1C or equivalent)	//////	
	HDL Cholesterol	//////	
	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
CHEMISTRY, Continued		//////	//////
	Magnesium	//////	
	Myoglobin	//////	
	pCO_2 (Blood Gas)	//////	
	pH (Blood Gas)	//////	
	Phosphorus	//////	
	pO_2 (Blood Gas)	//////	
	Potassium	//////	
	Protein Electrophoresis	//////	
	PSA	//////	
	Sodium	//////	
	Total Protein	//////	
	Triglycerides	//////	
	Troponin	//////	
	Urea Nitrogen (BUN)	//////	
	Uric Acid	//////	
		//////	
		//////	
		//////	
PARASITOLOGY			//////
	Blood Parasite	//////	
	Fecal Suspension (Wet Mount)	//////	
	Fecal Suspension (Giardia and/or Cryptosporidium Immunoassay)	//////	
	Giemsa-stained Blood Smear	//////	
	Parasite Identification	//////	
	Tissue Parasite Identification	//////	
		//////	
		//////	
		//////	
VIROLOGY			//////
	Adenovirus Antigen	//////	
	Cytomegalovirus (CMV)	//////	
	Enterovirus	//////	
	Herpes Simplex Virus (Antigen Detection)	//////	
	Herpes Simplex Virus Culture	//////	
	Human Papillomavirus (HPV)	//////	
	Influenza Viruses	//////	
	Parainfluenza Type 2 Antigen	//////	
	Parainfluenza Viruses	//////	
	Rapid Flu	//////	
	Rotavirus Antigen	//////	
	RSV	//////	
	Varicella-Zoster Virus	//////	
	Viral Antigen Detection	//////	
	Viral Isolation/Identification	//////	
		//////	
		//////	
		//////	

X	Specialty / Subspecialty	No. of Tests Performed Annually	Check (X) if CLIA Waived
ENDOCRINOLOGY			//////
	Cortisol	//////	
	Estradiol	//////	
	Free Thyroxine	//////	
	FSH	//////	
	HCG (Serum Pregnancy or Non-Waived Urine HCG)	//////	
	Luteinizing Hormone	//////	
	Progesterone	//////	
	T3 or T Uptake	//////	
	Testosterone	//////	
	Triiodothyronine (T3)	//////	
	TSH	//////	
	Thyroxine (T4)	//////	
		//////	
		//////	
		//////	
TOXICOLOGY/TDM			//////
	Blood Alcohol	//////	
	Blood Lead	//////	
	Carbamazepine	//////	
	Digoxin	//////	
	Drugs of Abuse Confirmatory	//////	
	Drugs of Abuse Screen	//////	
	Ethosuximide	//////	
	Gentamicin	//////	
	Lithium	//////	
	Phenobarbital	//////	
	Phenytoin	//////	
	Primidone	//////	
	Procainamide/Metabolites	//////	
	Quinidine	//////	
	Theophylline	//////	
	Tobramycin	//////	
	Urine Alcohol	//////	
	Valproic Acid	//////	
		//////	
		//////	
		//////	
IMMUNOHEMATOLOGY *			//////
	ABO Group	//////	
	D (Rh) Typing	//////	
		//////	
		//////	
		//////	

(***** Only for sites not collecting and /or transfusing blood products)

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

LABORATORY TESTS PERFORMED, Continued

X	Specialty / Subspecialty	No. of Tests Performed Annually	Check (X) if CLIA Waived
DIAGNOSTIC IMMUNOLOGY			//////
	AFP/Other	//////	
	AFP/Tumor Markers	//////	
	Allergy Testing	//////	
	Alpha-1 Antitrypsin	//////	
	ANA	//////	
	ASO	//////	
	C3	//////	
	C4	//////	
	Flow Cytometry	//////	
	H. pylori	//////	
	Hepatitis A Virus Antibody	//////	
	Hepatitis B Core Antibody	//////	
	Hepatitis B Core Antigen	//////	
	Hepatitis B Surface Antibody	//////	
	Hepatitis B Surface Antigen	//////	
	Hepatitis Be Antigen	//////	
	Hepatitis C	//////	
	Hepatitis C Virus Antibody	//////	
	HIV	//////	
	IgA	//////	
	IgE	//////	
	IgG	//////	
	IgM	//////	
	Infectious Mononucleosis	//////	
	Rheumatoid Factor	//////	
	Rubella Antibody	//////	
		//////	
		//////	
SYPHILIS SEROLOGY			//////
	FTA	//////	
	MHA-TP (TP-PA)	//////	
	RPR	//////	
	VDRL	//////	
		//////	
		//////	
HEMATOLOGY			//////
	Activated Clotting Time	//////	
	CBC (Complete Blood Count)	//////	
	Automated WBC Differential	//////	
	RBC	//////	
	Hematocrit (excluding Spun Microhematocrit)	//////	
	Hemoglobin (excluding Copper Sulfate)	//////	

X	Specialty / Subspecialty	No. of Tests Performed Annually	Check (X) if CLIA Waived
HEMATOLOGY, Continued		//////	//////
	WBC	//////	
	Platelet Count	//////	
	Cell Identification/Manual Differential	//////	
	D-dimer	//////	
	ESR (Automated)	//////	
	ESR (Non-automated)	//////	
	Factor Assays	//////	
	Fecal Occult Blood	//////	
	Fibrinogen	//////	
	INR	//////	
	Prothrombin Time	//////	
	PTT	//////	
	QBC Hematology	//////	
	Reticulocyte Count	//////	
	Semen Analysis/Count	//////	
	Thrombin Time	//////	
		//////	
		//////	
		//////	
CYTOLOGY			//////
	GYN	//////	
	Non GYN	//////	
	Urine	//////	
		//////	
		//////	
		//////	
GENETICS AND/OR TISSUE TYPING			//////
	Biochemical Genetic Tests (List Tests)	//////	
		//////	
		//////	
		//////	
	Cytogenetic Tests (List Tests)	//////	
		//////	
		//////	
		//////	
	Molecular Genetic Tests (List Tests) (Add HPV Testing under Virology)	//////	
		//////	
		//////	
		//////	
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.

☐ Category I 1-9 Employees **$200**	☐ Category II 10-29 Employees **$250**	☐ Category III 30-49 Employees **$300**	☐ Category IV 50-89 Employees **$350**	☐ Category V 90 or More Employees **$400**

Specialty(ies) Offered by Laboratory

☐ Urinalysis
☐ Bacteriology
☐ Mycobacteriology
☐ Parasitology
☐ Mycology
☐ Virology
☐ Diagnostic Immunology (includes General Immunology and Syphilis Serology)
☐ Hematology
☐ Immunohematology *
☐ Chemistry
☐ Endocrinology
☐ Toxicology/TDM
☐ Cytology
☐ Genetics and/or Tissue Typing

Total Number of CLIA Non-Waived Specialties Checked: _____ (***** Only for sites not collecting and /or transfusing blood products)

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