

Public Health & Environmental Laboratories

Change of Specialty/Test

How to Request a Change in Specialty/Test with ALiS

NJDOH Clinical Laboratory Licensing Program

Dear Clinical Laboratory Licensee,

Please ensure that you read the following instructions completely before initiating the process to add a specialty/test.

Licensees must notify the Clinical Laboratory Licensing Program (CLLP) within 30 business days of any modifications to their non-waived test menu, whether additions or deletions. Failure to properly submit these requests may lead to delays in the review and approval process. Please be advised that licensees must obtain formal approval from CLLP prior to starting patient testing for any new test.

ADD NEW SPECIALTY/TEST

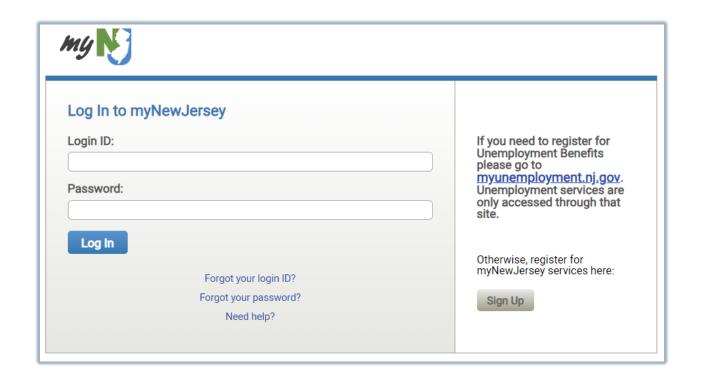
Items required to complete a specialty/test expansion request:

- An Official Request Letter from your Laboratory Director or Qualified Designee
 - Must include issuance date, laboratory name, CLIS ID #, specialties/tests to be added, and date director's/qualified designee's signature.
- Graded proficiency testing results
 - Must participate in off-cycle/pre-licensure events. If entirely inaccessible, a correlation (split sample) study with a licensed New Jersey clinical laboratory may be submitted. Contact <u>cllp@doh.nj.gov</u> for correlation criteria.
 - For Laboratory Developed Tests (LDTs), the laboratory is required to submit the complete validation study. Contact <u>cllp@doh.nj.gov</u> for validation criteria.

**Note: Laboratories are required to actively participate in off-cycle or pre-licensure proficiency testing events whenever possible.

- Licensure fee (if applicable)
 - Additional fees may be incurred for the addition of new tests/specialties. An invoice will be generated by ALiS upon application submission.

Step 1. Log in to your account using the following website address: https://my.nj.gov/aui/Login.



Step 2. Then click on the CLIS Licensing icon/link under DOH Applications.



Step 3: Click on the Change of Specialty/Test Module Link under the "What Do You Want To Do?" menu on your home page.



Step 4: Select Add New Specialty/Test as the application type then hit the "Next" button.



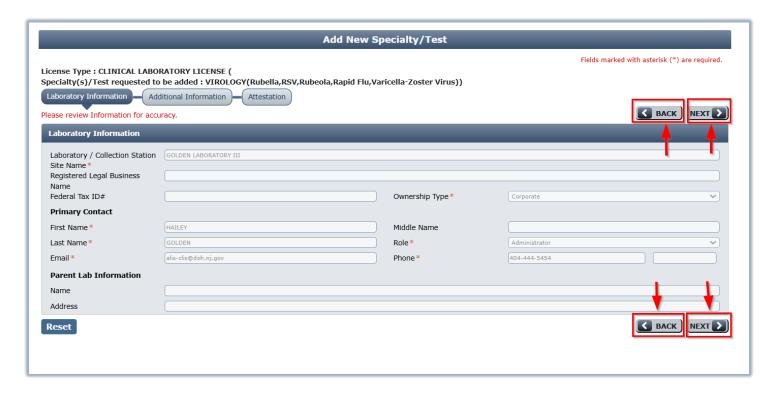
Step 5: The laboratory's current active license(s) and related information will be automatically populated.

Step 6: To add tests to your menu, select the desired test(s) under each specialty by clicking the box to the left of the test name. After you have completed your selections, click the "Next" button to proceed. If you wish to clear your selections and begin again, use the "Reset" button.

If a test is not listed, please contact CLLP program directly by emailing cllp@doh.nj.gov.

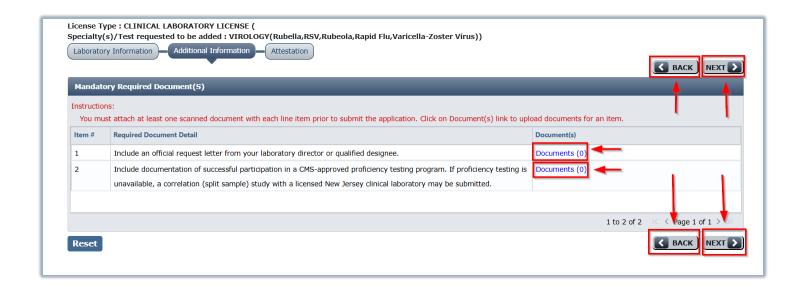
| ✓ VIROLOGY | | |
|--------------------------------------|--|---|
| 2019-nCoV Coronavirus | 2019-nCoV Coronovirus Waived | Adenovirus Antigen |
| ☐ Astrovirus | ☐ BK virus by PCR technique | ☐ Bocavirus |
| ☐ chikungunya | Coronavirus | Coronavirus 229E |
| Coronavirus HKU1 | Coronavirus NL63 | Coronavirus OC43 |
| Coxsackiervirus A&B (2 volumes) | Cytomegalovirus (CMV) | ☐ Dengue |
| ☐ Ebola Viruses | ☐ Echovirus | ☐ Enterovirus |
| ☐ Epstein-Barr | ☐ Epstein-Barr Virus (EBV) DNA by PCR | ☐ Epstein-Barr Virus DNA Quantitative Real-Time PCR |
| ☐ HBV Genotyping | ☐ HBV RDv2 | ☐ HCV |
| ☐ Hepatitis-C Virus by Real-Time PCR | ☐ Herpes Simplex | ☐ Herpes Simplex Virus (Antigen Detection) |
| ☐ Herpes Simplex Virus Culture | ☐ HIV Viral Load | ☐ HIV-1 |
| ☐ HPV 16/18 | ☐ HPV-ISH | ☐ Human Herpesvirus |
| ☐ Human Herpesvirus-6 | ☐ Human Metapneumovirus | ☐ Human Papillomavirus (HPV) |
| ☐ Human Rhinovirus/Enterovirus | ☐ Influenza A | ☐ Influenza A 2009 H1N1 |
| ☐ Influenza A/B with A subtyping | ☐ Influenza B | ☐ Influenza C |
| ☐ Influenza Viruses | Lyme Disease | ☐ Measles Virus |
| ☐ MERS | ☐ Mumps Virus | ☐ Norovirus, DNA |
| ☐ Parainfluenza | Parainfluenza Type 2 Antigen | Parainfluenza Virus 1 |
| Parainfluenza Virus 2 | Parainfluenza Virus 3 | Parainfluenza Virus 4 |
| ☐ Parainfluenza Viruses | ☐ Parechovirus | Parvovirus B19 Antibodies |
| Rapid Flu | Respiratory Syncytial Viruses A&B(HRSVA/B) | Rhinovirus |
| ☐ Rotavirus Antigen | ✓ RSV | Rubella |
| Rubeola | ☐ Sapovirus | ✓ Varicella-Zoster Virus |
| ☐ Viral Antigen Detection | ☐ Viral Isolation/Identification | west nile virus |
| XTAG Respiratory Virus Panel (RVP) | Zika Virus | |

Step 7: Carefully review each section, including Laboratory Information, Additional Information, and Attestation, to ensure accuracy. Use the "Next" button to save your entries and proceed to the next section. To return to a previous section, click the "Back" button.

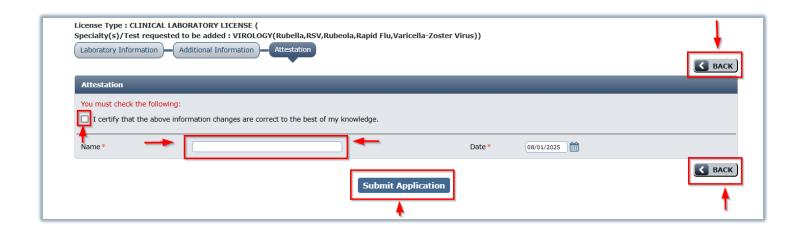


To update the laboratory's information, please notify CLLP by emailing cllp@doh.nj.gov prior to submitting your application. Ensure that your facility's name and CLIS ID number are included in the subject line or body of the email.

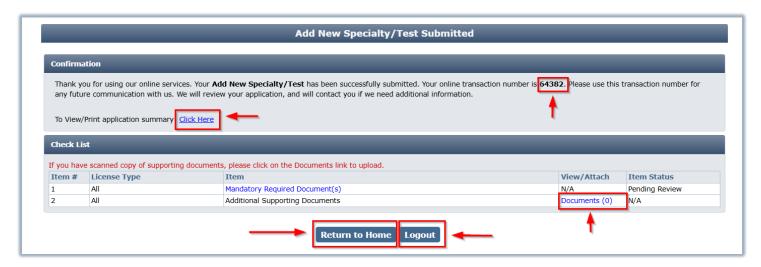
Step 8: Complete the additional information section by attaching the required scanned documents. Use the Document link (in blue) to upload the document. Then follow the instructions for uploading a document (in red). Note: The maximum file size for uploading is 5MB. For larger files, please email cllp@doh.nj.gov for further instructions. Click on the "Next" button to save entries and move forward to the next section.



Step 9: Please ensure the application is thoroughly reviewed prior to submission. Complete the attestation by reading and then checking the box located to the left-side of the statement. The applicant must enter his or her name, select the date, and click on the Submit Application button. The Back button can be used to move back to the previous section.

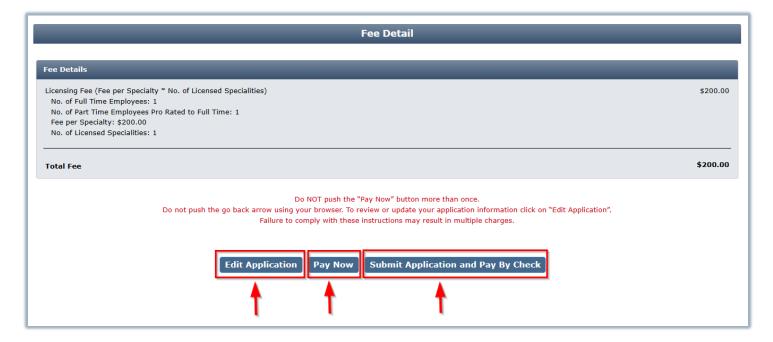


Step 10a: If no additional fees are owed, a confirmation page will be displayed. **It is essential to print the application summary from this page.** Additionally, applicants should record their online transaction number for future reference. Applicants may also upload additional supporting documents by utilizing the documents link.



Step 10b: Additional fees may be incurred for the addition of new specialties/tests. ALiS will calculate the fee. The "Fee Detail" page will appear. It provides the fee details and the total fee owed for your specialty/test change. There are three options at the bottom of the page: "Edit Application", "Pay Now", and "Submit Application and Pay By Check".

Please be advised that all fees are non-refundable. Kindly ensure the accuracy of all payments prior to submission.



Edit Application

Allows the licensee to make modifications to the application.

Payment Options

The "Pay Now" button facilitates electronic payments (ePayment) for the specialty/test change fee.

- A) Selecting the credit card option redirects you to the State of New Jersey Payment Management Services webpage, where you will complete the customer billing and credit card information.
- B) Selecting the eCheck option reveals an "eCheck Information" box. Complete the required information fully, then click on the "Next" button. You will be prompted to confirm the accuracy of the entered information. Click "OK" to proceed or "Cancel" to make changes.
- C) The submit application and pay by check allows you to submit the specialty/test change request and then mail a paper check to CLLP. **Please issue checks payable to New Jersey Department of Health or NJDOH.**

****When submitting a paper check, please include a copy of the ALiS-generated invoice, along with the corresponding CLIS ID number. Non-compliance with these requirements may result in additional delays in the processing of specialty/test change requests.****

For mailing or shipping paper checks, please use the following address options:

Return Address (USPS):

NJDOH, Public Health & Environmental Laboratories ATTN: Joan Mikita Clinical Laboratory Licensing Program PO BOX 361 Trenton, NJ 08625-0361

Return Address (FedEx/UPS):

NJDOH, Public Health & Environmental Laboratories ATTN: Joan Mikita Clinical Laboratory Licensing Program 3 Schwarzkopf Drive Ewing, NJ 08628 Upon submitting payment, a confirmation page will be displayed. It is essential to print the payment receipt or invoice and the application summary from this page. Additionally, applicants should record their online transaction number for future reference. Applicants may also upload additional supporting documents by utilizing the documents link.

Please be advised that once an application is submitted through ALiS, its status can be monitored within the "View Pending Online Applications" module. This module allows users to reprint their application summary and upload any supplementary documentation via the "View Details" function. Also note that the "Withdraw" function is currently disabled; therefore, users must contact CLLP directly (cllp@doh.nj.gov) to withdraw a submitted application.

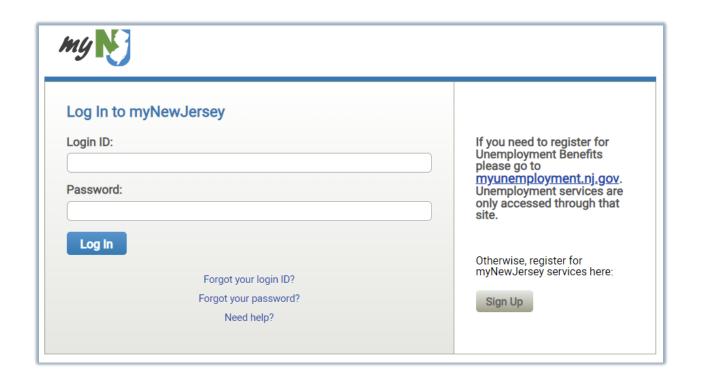
Step 11: Your application will be forwarded for review, and you will receive a confirmation email from ALiS acknowledging receipt. Upon approval by CLLP, you will receive a notification email, followed by correspondence containing an approval letter and, if applicable, an amended license.

REMOVE SPECIALTY/TEST

Items required to delete a specialty/test:

- An Official Request Letter from your Laboratory Director or Qualified Designee
 - Must include issuance date, laboratory name, CLIS ID #, specialties/ tests to be removed, effective date, and dated director's/qualified designee's signature.

Step 1. Log in to your account using the following website address: https://my.nj.gov/aui/Login.



Step 2. Then click on the CLIS Licensing icon/link under DOH Applications.



Step 3: Click on the Change of Specialty/Test Module Link under the "What Do You Want To Do?" menu on your home page.

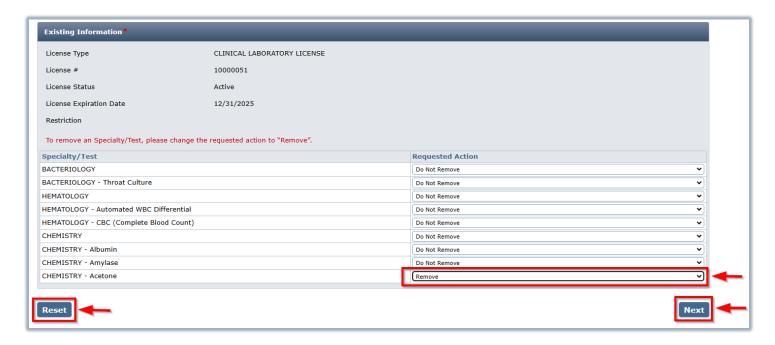


Step 4: Select Remove Existing Specialty/Test as the application type.



Step 5: The laboratory's current active license(s) and related information will be automatically populated.

Step 6: To remove tests and/or specialties from your test menu, select "Remove" under the requested action dropdown menu. After you have completed your selections, click the "Next" button to proceed. If you wish to clear your selections and begin again, use the "Reset" button.

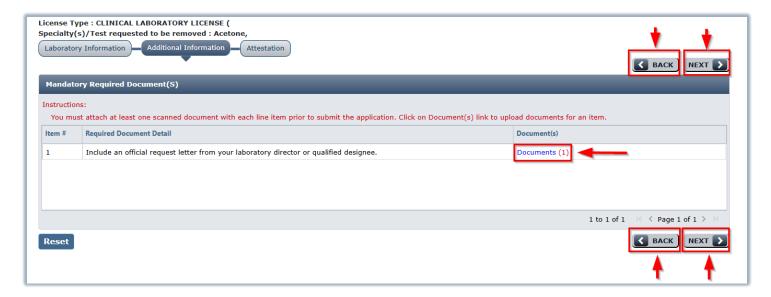


Step 7: Carefully review each section, including Laboratory Information, Additional Information, and Attestation, to ensure accuracy. Use the "Next" button to save your entries and proceed to the next section. To return to a previous section, click the "Back" button.

| Remove Existing Specialty/Test | | | | | |
|---|----------------------|-----------------|------------------|--|--|
| Fields marked with asterisk (*) are required. icense Type: CLINICAL LABORATORY LICENSE (pecialty(s)/Test requested to be removed: Acetone, | | | | | |
| Laboratory Information — Additional Information — Attestation Please review Information for accuracy. | | | | | |
| Laboratory Information | | | | | |
| Laboratory / Collection Station Site Name * | GOLDEN LABORATORY II | | | | |
| Registered Legal Business Name | | | | | |
| Federal Tax ID# | | Ownership Type* | Corporate | | |
| Primary Contact | | | | | |
| First Name* | HAILEY | Middle Name | | | |
| Last Name* | GOLDEN | Role * | Person In charge | | |
| Email* | alis-clis@doh.nj.gov | Phone* | 404-444-5454 | | |
| Parent Lab Information | | | | | |
| Name | | | | | |
| Address | | | | | |
| Reset | | | BACK NEXT > | | |

To update the laboratory's information, please notify Clinical Laboratory Licensing by emailing cllp@doh.nj.gov prior to submitting your application. Ensure that your facility's name and CLIS ID number are included in the subject line or body of the email.

Step 8: Complete the additional information section by attaching the required scanned documents. Use the Document link (in blue) to upload the document. Then follow the instructions for uploading a document (in red). Note: The maximum file size for uploading is 5MB. For larger files, please email <u>cllp@doh.nj.gov</u> for further instructions. Click on the "Next" button to save entries and move forward to the next section.



Step 9: Please ensure the application is thoroughly reviewed prior to submission. Complete the attestation by reading and then checking the box located to the left-side of the statement. The applicant must enter his or her name, select the date, and click on the Submit Application button. The Back button can be used to move back to the previous section.



Step 10: After submitting the attestation, a confirmation page will be displayed. **It is essential to print the application summary from this page.** Additionally, applicants should record their online transaction number for future reference. Applicants may also upload additional supporting documents by utilizing the documents link.



Please be advised that once an application is submitted through ALiS, its status can be monitored within the "View Pending Online Applications" module. This module allows users to reprint their application summary and upload any supplementary documentation via the "View Details" function. Also note that the "Withdraw" function is currently disabled; therefore, users must contact CLLP directly (cllp@doh.nj.gov) to withdraw a submitted application.

Step 11: Your application will be forwarded for review, and you will receive a confirmation email from ALiS acknowledging receipt. Upon approval by CLLP, you will receive a notification email, followed by a correspondence containing an amended license, if applicable.