

Purpose:

The purpose is to approve laboratories providing blood cholinesterase analysis and data management services in support of [WAC 296-307-148](#), Cholinesterase Monitoring. This rule requires employers using pesticides which may suppress cholinesterase to conduct medical monitoring for those employees working with the pesticides. Employers must have the testing conducted in a timely manner and must use the same laboratory for all tests of an individual.

Key considerations in approving a laboratory are:

- The laboratory must be licensed through the Laboratory Quality Assurance program administered under the Washington State Department of Health. The licensure must cover the laboratory's work with cholinesterase testing and quality assurance for this work. Additionally, accreditation of the laboratory through the College of American Pathologists is preferred.
- Cholinesterase blood samples are time sensitive. The laboratory must have systems in place for working with medical providers to receive and analyze samples within the time frame given in the rule. The laboratory will be expected to support medical providers with information on protocols and testing procedures.
- The laboratory services will be equitable and cost effective for workers and employers.
- The laboratory must have a system in place for collecting information on tested workers and capable of transmitting/communicating that information securely to the Washington State Department of Labor & Industries Division of Occupational Safety and Health (DOSH). This provides a mechanism for employer's to meet the requirement to submit this information to the department.
- The department tracks the statewide monitoring of workers and has an interest in minimizing the number of laboratories supporting the program to provide clear direction to employers and medical providers, give consistent results across the monitored community, and best support the department's goal to keep Washington Safe and Working.

Scope of services:

The laboratory will provide blood cholinesterase testing in support of [WAC 296-307-148](#), Cholinesterase Monitoring, maintain electronic records of cholinesterase test results and supportive data, and provide for secure transfer of data files to Washington State's Department of Labor & Industries Division of Occupational Safety and Health (DOSH) on a weekly basis. The approved laboratory is designated as an approved laboratory under [WAC 296-307-14815](#).

The services must be provided throughout the annual testing season. The season begins in the third week of January and goes through the end of September each year. The approved laboratory will work with DOSH staff to set specific dates and provide materials for communication with the medical providers about testing protocols and procedures.

Duties and Required Reports:

Brief descriptions of the duties and required reports are set out below. Because the approved laboratory will be controlling the manner and means of conducting the work, the descriptions are not intended to completely describe all of the work that the laboratory would need to perform to complete the duties.

1. Performing red blood cell and serum cholinesterase laboratory analysis. The laboratory is responsible for determining analytical operating procedures and data management/quality control procedures used for this work. The procedures must be covered by the laboratory's Washington State Medical Test Site license.
2. Monitoring client services and working with clients to ensure appropriate and complete test requisition, specimen collection, handling and storage. All discrepancies within the defined operating procedures and the corrective actions taken shall be reported to DOSH within 30 days of first discovery.
3. Provide for Analytical Operating Procedures development and Data Management/Quality Control activities in consultation with DOSH Technical Staff.
4. Participate in cholinesterase testing program stakeholder meetings. These meetings will be arranged by the department as needed. The laboratory will be notified of any meetings at least 60 days prior to the meeting
5. Reporting of patient test results to providers on an average of less than or equal to four (4) days from the specimen receipt.
6. Providing DOSH with Data Management/Quality Control activity reports and Performance Measurement Reports.
7. Maintaining electronic data files of all tests performed that are coded to the individual patient, including relevant demographic data and cholinesterase activity percent change relative to baseline. The approved laboratory will provide secure data file transfer to the DOSH Industrial Hygiene Technical Services on a weekly basis. In addition, the laboratory will provide DOSH with access to individual test reports via its secured server site. Minimum data provided will include:

Farm worker first name

- 7.1 Farm worker middle name
- 7.2 Farm worker last name
- 7.3 Farm worker ID code
- 7.4 Mother's maiden and first names
- 7.5 Clinic name, address, and telephone number
- 7.6 Ordering provider

- 7.7 Employer ID Code
- 7.8 Employer name, address, and telephone number
- 7.9 Employer contact name
- 7.10 Sample collection date
- 7.11 Test designation (baseline, working baseline, periodic)
- 7.12 Sample accepted or rejected, and reason
- 7.13 Test accession number
- 7.14 Sample run date
- 7.15 Sample receiving temperature
- 7.16 RBC ChE result
- 7.17 Serum ChE result
- 7.18 Pesticide handling hours 30 days prior to testing and total year to date
- 7.19 Result report date

8. Conducting individual case follow-up as needed in order to clarify or obtain missing information on the test requisition form.

Reimbursement of Costs:

All costs associated with routine testing services under [WAC 296-307-148](#) shall be charged to the patient’s provider.

Performance Measurement and Monitoring:

The approved laboratory is responsible for evaluating performance and quality of their analysis. Quality assurance reports covering cholinesterase related services must be submitted to DOSH as they are completed and no later than one month following the testing season.

Annual Schedule

- October 31 – Laboratory request letters due (i.e. laboratories seeking approval for Cholinesterase Monitoring)
- December 15 – Department notification of approved laboratories.
- 3rd week of January – Beginning of testing for the year (See sample letter that goes out to medical providers from approved laboratories.)
- Last week of September – End of testing for the year
- October 31 – Final QA/QC Reports due to the department

Proprietary Information:

DOSH is subject to chapter 42.56 RCW, the Public Records Act and approval documents will be a public record as defined in RCW 42.56. Any specific information submitted to DOSH and claimed by the

laboratory to be confidential or proprietary, must be clearly identified as such by the laboratory. To the extent consistent with chapter 42.56 RCW, DOSH shall maintain the confidentiality of all such information marked confidential or proprietary. If a request is made to view the laboratory's proprietary information and DOSH intends to release the information, DOSH will notify the laboratory of the request and notify the laboratory of the date that such records will be released to the requester. It will be the responsibility of the laboratory to obtain any necessary court order enjoining that disclosure. If the laboratory fails to obtain the court order enjoining disclosure, DOSH will release the requested information.

Application for approval:

Laboratories must submit a letter requesting approval with the following information.

1. Name, credentials, and contact information for the individual responsible for oversight and quality of cholinesterase laboratory analysis.
2. Name and contact information for the organization business contact responsible for coordinating with DOSH staff.
3. Laboratory licensing and accreditation information specific to RBC and serum cholinesterase analysis.
4. Laboratory cost schedule for testing services.
5. Details on how required records will be transmitted or made available to DOSH. Transfer of data must be done in a secure manner to provide confidentiality for the test results.
6. The laboratory's Analytical Operating Procedures and Data Management/Quality Control Procedures.

DOSH will advise the laboratory of any errors or concerns before final approval and may ask for additional documentation or information.

Submission of Application for Laboratory Approval must be delivered electronically or by email to Kat Gregerson, grka235@lni.wa.gov.