

DIAGNOSTIC IMMUNOLOGY AND HIV PROFICIENCY TESTING PROGRAM

General Instructions

Please read these instructions carefully. It is essential that you read these instructions before processing the proficiency test samples you have received for Diagnostic Immunology and/or HIV.

You should consider the samples potentially infectious and use CDC recommended precautions during processing. Excess test material and damaged or leaking specimen containers must be autoclaved or treated with an appropriate disinfectant. All samples are human plasma. Please refrigerate them on receipt.

On Receipt of Proficiency Test Specimens:

- Check that sample vials are intact and plasma has not leaked.
- Make certain you have received samples for each analyte processed in your laboratory for which we offer proficiency testing. The analyte list included with your shipment lists all the analytes we offer PT for. Your lab should have received samples for only the analytes that you offer. If you did not receive samples for an analyte that you process or if you received samples for an analyte you do NOT process please inform our office at once by calling **518-474-4177**. In addition, if the samples are unsatisfactory or vials are missing, call us for replacement samples before the replacement deadline given.
- If you need to **add or delete** an analyte from your protocol you need to complete the form “Notification to Add/Remove Analytes” which can be obtained by downloading from <http://www.wadsworth.org/labcert/clep/Administrative/chngaddanalyte.pdf> or by calling CLEP at 518-485-5378. If the analyte being deleted is subject to proficiency testing, the laboratory should inform the program no less than two weeks prior to the shipment of the next proficiency test event by submitting the appropriate forms.
- Proficiency test samples must be logged in and tested along with patient specimens as part of the normal laboratory procedure by employees who routinely perform these tests. Do not perform any special tests that are not normally performed on clinical specimens, such as repeated tests or additional confirmatory tests. You must report results from only one test system/kit per analyte. However, now ANA, ASO, RF and Rubella have a separate quantitative analyte so you may report results from a different system/kit than was used for the qualitative analyte. **Note:** you are responsible for testing alternate/additional systems for equivalency as per **Quality Assurance Standard 15**.
- If you only report qualitative results on patient samples then report only qualitative results on the PT. If your laboratory reports quantitative AND qualitative results on patient samples then report both on the PT samples. You will then be graded separately on both. Quantitative and semi-quantitative results expressed as dilutions (titers, etc.), IU/ml, and mg/dl only are used in grading. You may report only quantitative results on some analytes (ANA, ASO, RF and Rubella) if acceptable units are reported. **Other quantitative values such as indexes and ratios are not used in grading, please make a qualitative interpretation.**
- When using a confirmatory test (WB, neutralization, etc), test only the specimens you would normally test for patient samples. You do not need to process all samples using the confirmatory test if you would normally process only reactive samples. If you did not process negative or nonreactive samples with the confirmatory system then report them as not applicable (NA). However, if your laboratory does NOT use a screening test prior to confirmatory testing then you must still process all samples with the confirmatory test.
- The attestation statement can be printed from the electronic result reporting form. You must keep signatures on file in your facility, do not return paper copies to the PT section. The attestation statement must be signed by the director or responsible assistant director and all technologists who processed the test sample(s).
- A drop down list of systems/test kits is now available with the online reporting form. If your system is not listed please indicate “other” on the online report form and provide us with the **manufacturer, kit name and methodology** in the comment field provided so that we can grade

your results properly. We will update our list accordingly.

Syphilis Reagin Ab Test: Laboratories testing for Syphilis reagin Ab in the category Diagnostic Services Serology must titer to the end-point all specimens found reactive, even if these are referred for confirmation. Arbitrary cutoff titers (e.g.>1:512) are not acceptable. **Any laboratory that does not titer to the endpoint will receive a grade of zero percent (0%).** Exceptions to this as per Diagnostic Immunology Standard 4 can be obtained by writing to CLEP prior to the test event.

NOTE: Donor samples need not be titered for Syphilis reagin Ab, unless results are given to the donor and reported to the State Health Department as mandated under Section 2102 of the Public Health Law. If results are given to the donor, the samples must be titered but it does not have to be done on site.

Grading Criteria

- Results for analytes your laboratory tests, which are left blank, will be considered incorrect and be given a score of 0%. If, for some reason, your laboratory is unable to process the samples for an analyte please notify us prior to submission of test results.
- Each analyte tested contains five samples, and twenty points are deducted for each incorrect result. For Syphilis Reagin tests, a titer reported out of range will have ten points deducted if the qualitative interpretation of positive is correct. Otherwise, each sample is worth twenty points and a failure to titer positive samples is a failure for Syphilis Reagin in that test event.
- For Diagnostic Services, failure to attain an overall testing score of at least 80% is unsatisfactory performance
- For Donor Services, failure to attain an overall testing score of 100% is unsatisfactory performance.
- For HIV, failure to attain an overall testing score of 100% is unsatisfactory performance.
- The laboratory that fails two out of three consecutive proficiency test events for an analyte or for the permit category will fail the proficiency testing program for the analyte or for the permit category and may be required to cease patient testing for that analyte/category.

Submission of Results

- Results must be submitted online no later than the posted deadline.
- Please do not return the paper worksheets. Paper result forms are no longer accepted unless permission has been given by the Clinical Laboratory Evaluation Program (CLEP) prior to the test event. Please contact CLEP at: clepeptrs@health.state.ny.us

Contact us

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Questions, comments and concerns should be addressed to the Diagnostic Immunology/ HIV Proficiency Testing Program at 518-474-4177 or DIPT@wadsworth.org. You can also visit us at http://www.wadsworth.org/divisions/infdi/di_hiv/index.html