

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2005935	(X3) Date Survey Completed 05/06/2022
Name of Provider or Supplier Wadsworth Center - Griffin Laboratory	Street Address, City, State New York State Department Of Health, Slingerlands, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of procedure manual and staff interview the laboratory failed to provide a standard operating procedure (SOP) for the ABI 7500 PCR instrument approved and signed by the current laboratory director (LD). Findings include: 1. The surveyor requested the current in-use procedure manual used by the Rabies section of the Griffin Laboratory. 2. On 05/06/2022 at approximately 12:40PM during a review of the in-use procedure manual, the SOP for the maintenance of ABI 7500 series revealed the most up to date signature and approval occurred in 2013 by the previous laboratory director. 3. During an interview with the laboratory staff confirmed the Griffin Laboratory does not have updated , approved and signed procedures by the current LD for the ABI 7500 Series.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test</p>

system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on lack of documentation, record review and staff interview the laboratory failed to document calibration verification for the ABI 7500 PCR instrument utilized in the molecular section of the Rabies laboratory. Findings include: 1. On 05/06/2022 at approximately 12:30PM during a record review of ABI 7500 PCR instrument calibration verification records revealed the laboratory failed to document the Pure Dye Calibration procedure as recommended in accordance with the Standard Operating Procedure for the ABI 7500 PCR Instrument for every 6 months. 2. The surveyor requested documentation of the calibration verification for the ABI 7500 PCR instruments for the year 2020-2022. 3. An interview with the general supervisor (GS#1) confirmed the laboratory did not perform and document calibration verification performance test on the ABI 7500 PCR instruments.

D5477

CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on the review of the arbovirus laboratory reagent logs, lack of media quality control (QC) records and interview with testing personnel (TP) #1, the laboratory failed perform and document each batch of 2x Eagles bic P/S +2% FBS and 2x Eagles bic P/S +10% FBS culture media for sterility and ability to support growth for the plaque reduction test from February 12, 2020 to March 31, 2022. Findings Include: 1. On the day of survey, 05/06/2022, TP #1 stated, all media is prepared from the core laboratory at 120 Scotland Avenue. 2. TP#1 stated, "a visually inspection of all received media is performed, but not documented". 3. Review of the arbovirus laboratory reagent logs and lack of media quality control (QC) records at approximately 9:30 am revealed, the following 2x Eagles bic P/S +2% FBS and 2x Eagles bic P/S +10% FBS culture media lots that were received by the laboratory from February 12, 2020 to March 31, 2022 were not QC by the laboratory: 2x Eagles bic P/S +2% FBS culture media. - 02/12/2020 - 06/15/2020 - 07/17/2020 - 08/12/2020 - 11/04/2020 - 02/09/2021 - 03/23/2021 - 04/28/2021 - 06/10/2021 - 06/24/2021 - 01

/25/2022 - 03/31/2022 2x Eagles bic P/S +10% FBS culture media. - 02/12/2020 - 06/15/2020 - 07/17/2020 - 08/12/2020 - 11/04/2020 - 02/09/2021 - 03/23/2021 - 04/28/2021 - 06/10/2021 - 09/08/2021 - 01/25/2022 - 03/31/2022 4. From February 12, 2020 to March 31, 2022, 79 plaque reduction tests were analyzed. 5. TP#1 confirmed viral culture media was not performed or documented for the plaque reduction test on May 6, 2022 at 12:30 pm.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on lack of documentation, record review and staff interview the laboratory failed to document corrective action for failed QC result for the Rabies SN test. Findings Include: 1. On 05/06/2022 at approximately 12:00pm during a review of a Rabie SN test data sheet records revealed a failed QC result for the 07/07/2020 TPB QC. 2. The surveyor requested the documentation of a repeated test run with corrected QC. 3. An interview with the technical supervisor (TS #1) confirmed the testing person did not document the corrective action of the duplicate testing following the failed Rabies SN Test QC result.