Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0658606	09/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Sc Dph Public Health Laboratory	8231 Parklane Road, Columbia, SC	

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
D0000	A recertification survey was conducted from 08/29/2023 through 09/01/2023. Additional documentation was requested for review on 09/07/2023, concluding the survey. Standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the laboratory' procedure, record review and interview with the Technical Supervisor of Virology, the laboratory failed to follow their own written policy in performing daily pipette cleaning tasks as part of work area preparation for 19 of 31 days in August 2023. Findings Include: a. A review of the laboratory's procedure titled, "Molecular Policies & Procedures Virology & Rabies Laboratory, Public Health Laboratory - SCDHEC" revealed on page 3 of 6 the following: "A. Work Area Preparation 1. Clean work surfaces where reagents will be prepared. Wipe down work surfaces with 2.5 to 3.5% (0.35M to 0.5M) sodium hypochlorite solution. Allow the sodium hypochlorite solution to contact surfaces for at least 1 1 minute and then follow with a deionized (D1) water rinse. Do not allow the sodium hypochlorite solution to dry. Cover the bench surface on which the reagents and samples will be prepared with clean, plastic-backed absorbent laboratory bench covers. 2. Clean a separate work surface where samples will be prepared. Use the procedure described above (Step A.1). 3. Clean any pipettors. Use the procedure described above (Step A. 1)." b. A review of the Biosafety Maintenance Log for the biosafety cabinet in Room 219 did not include instructions and documentation of A.3, pipette cleaning for the following dates where the work area was utilized: August 1-3, August 7-9, August 14-

	18, August 21-25, August 28-31 c. An interview with the Technical Supervisor of Virology on 08/31/2023 at 11:19 AM in Room 219 confirmed these findings. Word Key: SCDHEC - South Carolina Department of Health & Environmental Control
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, NeoBase corrective action, and in interview with the technical supervisor, the laboratory failed to have a written procedure for corrective actions to take when NeoBase quality control (QC) was outside of their defined acceptability. Findings included: 1. Review of the laboratory's "QA Manual" policy (index number QA-POL-12) stated, "e ...6) Procedure for troubleshooting failed QC is in the SOP and follow-up documentation should be completed according to the PHL QA Manual and each section's SOP." Review of the laboratory's "NeoBase SOP" procedure (index number NBS-SOP-26) did not include written troubleshooting instructions for failed QC. 2. Review of "Quality Control or Preventive Maintenance Failure/Non-compliance Documentation" for NeoBase included documented corrective actions in 01/2023, 05/2023, and 07/2023 (random sampling): 01/04/2023 - "003-1 QC Failure; Re-Punch and run; 003-1RP rejected due to high SA 003-1RP2 run 1/5/23 passed." 01/18/2023 - "017-RT C2 high QC out; Re-punch and repeated as Plate as 017-RTRP on QM#4; Plate 017-RTRP rejected due to replicate inconsistences and low intensities. Please see 1/19/23 entry." 01/19/2023 - "Plate 017-3RP failed due to multiple low and high QC analyte values outside normal limits. Plate 017-RTRP rejected due to replicate inconsistencies and low intensities; Re-punch and repeated as Plate 017-3RP2 and 017-RTRP2 on QM#3; Plate 017-RTRP2 and 017-3RP2 accepted. All QC and patient samples released." 05/11/2023 - "129-1, 129-2 had multiple bad chromatograms and were set-up on the same day as the 128-RT, 129-knowns. No QC was recorded because plates were accepted in RV; 129-1, 129-2 plates were repunched and ran as 129-1RP, 129-2RP; Plates acceptable. All QC and Patient results released." 07/07/2023 - "Plate 187-RT Failed on QM#3 due to Both Low and High QC was outside normal limits for LEU; Re-punch and Repeat Plate as 187-RTRP; Plate 187-RTRP acceptable. All QC and patient results released." The laboratory did not implement a written QC procedure that included corrective

	actions taken when QC was not within the defined acceptability. 3. During an interview on 09/01/2023 at 1:20 pm, newborn screen technical supervisor-3 confirmed the laboratory did not have a written procedure for corrective actions to take when NeoBase QC was outside of their defined acceptability. Word Key: QA - quality assessment POL - policy SOP - standard operating procedure PHL - public health laboratory NBS - newborn screen
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory maintenance records (July 1 - 31, 2023), test volume records, and interview with the General Supervisor of Diagnostic Serology, the laboratory failed to perform and document daily maintenance for 15 of 31 days on the Hologic Panther System analyzers in July 2023. Findings included: a. The manufacturer's instructions for the Hologic Panther System (AW-10867 Rev. 001) listed the following maintenance requirements: "It is required that this task be performed after each testing day. For example, if processing test orders on Monday-Friday, schedule the Mag Wash Clean task to be run after working hours on Monday-Friday." b. A review of the laboratory's maintenance record titled, "Panther Maintenance Log Report" from July 1, 2023 through July 31, 2023 revealed the laboratory failed to perform and document daily Mag Wash Clean maintenance for the following days testing was performed on the four Hologic Panther System Analyzers (Serial Numbers 10516, 10518, 10632, 10643): 7/03/23, 7/05/23, 7/06/23, 7 /10/23, 7/11/23, 7/12/23, 7/13/23, 7/14/23, 7/17/23, 7/18/23, 7/19/23, 7/20/23, 7/21 /23, 7/25/23, 7/28/23 c. In July 2023, the laboratory tested 2,729 Trichomonas vaginalis patient specimens on the four Hologic Panther System Analyzers. d. In an interview on 08/30/2023 at 2:00pm in the laboratory, and after review of the maintenance record, the General Supervisor of Diagnostic Serology confirmed the findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, BioRad Variant summary reports, patient final test reports, and in interview with the technical supervisor, the laboratory failed to include a positive control material for hemoglobin Barts on the BioRad Variant newborn screen test method for six of six patients (2022 and 2023). Findings included: 1. Review of the laboratory's "BioRad Variant SOP" (index number NBS-SOP-25) stated, "This test is used for: 1st tier screening of newborn specimens; 2nd

	tier screening of adult specimens with abnormal results" and "Calibration and Quality Control Requirements ...(2) All analyte peaks for the quality control samples (FAES and FADC) including hemoglobins as HbF, HbA, HbE, HbS, HbD, and HbC must be correctly detected and identified." The controls did not include hemoglobin Barts. 2. Review of BioRad Variant newborn screen "Summary Reports" and final test reports from 2022 and 2023 (random sampling) included the following newborn patients with reported Hemoglobin Barts (FAB, %) without positive control material: 07/04/2022 - Patient 20221831155, Hb pattern FAB 16.5% 10/04/2022 - Patient 20222761279, Hb pattern FAB 15.1% 10/07/2022 - Patient 20222791067, Hb pattern FAB 17.4% 10/07 /2022 - Patient 20222791156, Hb pattern FAB 10.3% 03/09/2023 - Patient 20230671012, Hb pattern FAB, 26.8% 05/01/2023 - Patient 20231191011, Hb pattern FAB, 10.8% 3. During an interview on 09/01/2023 at 1:20 pm, newborn screen technical supervisor-3 confirmed control material used for BioRad Variant test method did not include hemoglobin Barts. Word Key: Hb - hemoglobin
D5459	CONTROL PROCEDURES CFR(s): 493.1256(d)(5)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Each electrophoretic procedure include, concurrent with patient specimens, at least one control material containing the substances being identified or measured. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, hemoglobin gel worksheets, patient final test reports, and in interview with the technical supervisor, the laboratory failed to include one control material with Hemoglobin Barts when testing patient specimens via Isoelectric Focusing (IEF) test method for six of six patients (2022 and 2023). Findings included: 1. Review of the laboratory's "IEF SOP" (index number NBS-SOP-24) stated, "This method is used as the 2nd tier screening test for newborn dried blood spot specimens and is the 1st tier screening test for adult dried blood spot specimens" and "5. Quality Control, a. Controls: BioRad retention time markers FAES and FADC are used." The controls did not include hemoglobin Barts, they included hemoglobin's F, A, E, S, D, and C. 2. Review of "Hemoglobin IEF Gel Worksheets" and final test reports from 2022 and 2023 (random sampling) included the following newborn patients with reported Hemoglobin Barts (FAB, %) and without control material (with Barts): 07/04/2022 - Patient 20221831155, IEF Result FAB 16.5% 10/04/2022 - Patient 20222761279, IEF Result FAB 15.1% 10/07/2022 - Patient 20222791067, IEF Result FAB 17.4% 10/07/2022 - Patient 20222791156, IEF Result FAB 10.3% 03/09 /2023 - Patient 20230671012, IEF Result FAB, 26.8% 05/01/2023 - Patient 20231191011, IEF Result FAB, 10.8% Note: the % was obtained from the BioRad Variant newborn screen first tier method (Area % of Peak), control material with Barts was not included. Refer to D5449. 3. During an interview on 09/01/2023 at 1:20 pm, newborn screen technical supervisor-3 confirmed control material used for hemoglobin IEF did not include hemoglobin Barts. Word Key: FAB - hemoglobin fetal, adult, Barts