Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0661133	12/09/2020
Name of Provider or Supplier	**Street Address, City, State**	
Division Of Consolidated Laboratory Services	600 North 5th Street, Richmond, VA	

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	The Centers for Medicare and Medicaid Services (CMS) Philadelphia Regional Office CLIA Surveyors conducted an announced routine CLIA recertification survey at Virginia Division of Consolidated Laboratory Services (DCLS) on December 07,2020- December 09, 2020. The laboratory is on compliance with 42 CFR part 493 with standard level deficiencies cited:
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) documentation, corrective action, and interview with Technical Supervisor (TS#1), the laboratory failed to complete corrective action for unsatisfactory scores of PT result of Urine Cadmium. 1. In review of the internal blind PT records for Urine Cadmium, 2020 the laboratory results exceeded the acceptable limits of less than or equal to 20% difference. 2. PT reviewer stated that the cadmium result was outside of the acceptable limits and a repeat of the testing was required. The QA officer signed off on this documentation on April 28, 2020. On the date of the survey, December 7, 2020 the laboratory failed to provide evidence of completed corrective action. 3. The laboratories occurrence management standard operating procedure states within 60 days follow up will be completed. 4. In an interview on December 8, 2020 at 10:00 am, TS#1 stated that corrective action was still in progress and has not been completed.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed

	in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification documentation, Center for Disease Control and Prevention (CDC) protocol, and interview with Technical Supervisor (TS#1), the laboratory failed to demonstrate that they had performed stability study for Determination of Metals by ICP-MS before patient testing as evidence by: 1. The laboratory performed verification on "Determination of Metals by ICP-MS" via the CDC's Laboratory Response Network recommendation. The documentation did not include a stability study. 2. Based on a review of the laboratory's procedure "Determination of Metals in Urine by ICP-MS," stated "urine samples and standards should be kept frozen at -15 degrees Celsius or less until analysis is performed." 3. The CDC's protocol for "Urine Multi-Element ICP-DRC-MS" states that "Once received, store long term at less than or equal to -20 degrees Celsius until time for analysis." 4. In an interview on December 8, 2020 at 10:00 am, when asked about the differing storage requirements, TS #1 states they had not performed a stability study.
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 the quality control (QC) record review, review of the occurrence management protocol and procedures (P&P), and interviews with the Newborn Screening (NBS) technical supervisor (TS1), the laboratory failed to document corrective actions for instrument/ QC failures on the Newborn Screen Failed Runs-2019 "Failed Runs Report" for GALT failures in the months November 2019 and December 2019. On December 09, 2020 at approximately 3:30 PM, a CMS CLIA surveyor requested QC records for the Galt analyte performed on the Perkin Elmer Genetic Screening Processor (GSP) instrument for the months November 2019 and December 2019. 1.On instrument GSP-20210115, Assay Flags alerted on the instrument due to QC out of range. a.GSP- 20210115 on December 20, 2019 Galt Run ID: 119922 Assay Flagged: Repeat Assay: Elution failed 1:3s QC2 and 1:3s QC1. At 3:40, the surveyor asked for the corrective action log for the flagged event. TS1 retrieved "Failed Runs Report" log for November and December 2019. The log

	revealed the laboratory instrument failure and/or QC failure with no corrective actions in the log. 2. 24 Failure Occurrence documented a.7 of 24 Failure Occurrence described as instrument failure b.14 of 24 Failure Occurrence described as QC failure c. 0 of 24 Failure Occurrence documented corrective action On December 10, 2020 at approximately 10:00 am, the surveyor requested the corrective action standard operating procedure (SOP). The laboratory QA manger presented Occurrence Management (SOP). 3.Section VI. Corrections Line. D "Document Corrections in the Occurrence Management Workflow in Qualtrax" 4.Section VII. Corrective Action. Line. D "A corrective action must be initiated to document a deficiency discovered during an external assessment." At approximately 1:30 PM, during the exit interview with the laboratory director and laboratory staff on December 09, 2020, the findings of the lack of corrective action in the "Failure Runs Log" were confirmed.