

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2108705	(X3) Date Survey Completed 07/08/2021
Name of Provider or Supplier Huntington Ingalls Health And Wellness Center	Street Address, City, State 4500 Washington Avenue, Newport News, 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	An announced CLIA validation survey was conducted at Huntington Ingalls Health and Wellness Center on July 8, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), procedure manual, and an interview, the new laboratory director failed to document approval and review of the laboratory's procedures after assuming the role in November 2020 and up to the date of the inspection on July 8, 2021. Findings include: 1. During the entrance interview, the Senior Health Services Manager informed the inspector that laboratory directorship changed in November 2020. Review of the CMS 209 revealed that a previous laboratory director was identified as responsible for overseeing the laboratory from July 2019 to November 2020 (LD #1). The current laboratory director (LD #2) took over in November 2020 and signed the survey CMS 209 form. (See Personnel Code Sheet.) 2. The inspector requested to review the laboratory procedure manual and was provided viewing of an online Share Point procedure manual. Upon reviewing the following four (4) procedures, the inspector noted they were not signed/approved by LD #1 or LD #2: QuadMed Microscopic Examination of Urine Sediment; QuadMed Supervisor Review of Quality Control; QuadMed Guidelines for QA Documentation and Timeline; QuadMed Proficiency Testing. The inspector inquired regarding why the current or previous LD had not approved, signed, or dated the procedures. The manager stated at approximately 1:00 PM: "We are in the process of moving from the</p>

online Share Point procedures to Policy Tech which will be more user friendly for updates and director signatures." 3. In an exit interview with the Senior Health Services Manager at approximately 1:30 PM, the above findings were confirmed.

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 a review of instrument maintenance logs, manufacturer's user manual, lack of documentation, and an interview, the laboratory failed to perform and document hematology instrument semi-annual maintenance procedures for twenty-four (24) of 24 months reviewed. Findings include: 1. Review of the laboratory's Abbott Cell Dyn Emerald hematology maintenance logs revealed no documentation of performance of the semi-annual maintenance during the review timeframe of July 2019 to the date of the survey on 07/09/21. The inspector noted that the maintenance was recorded as performed on 02/12/19. The inspector requested additional documentation of the semi-annual maintenance procedures. The Senior Health Services Manager stated at approximately 11:00 AM: "Our field service representative may have performed it on their once annual preventative maintenance visits but I am not sure". No additional records of the semi annual maintenance was available for review. 2. Review of the Abbott Emerald Operations Manual revealed maintenance instructions that stated: "The syringe pistons are to be lubricated every six months". 3. In an exit interview with the Senior Health Services Manager at approximately 1:30 PM, the above findings were confirmed.

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on a tour, review of procedures, maintenance logs, lack of documentation, and an interview, the laboratory failed to document that the Unico centrifuge revolutions per minute (RPM) function check/verification met the urinalysis sediment examination protocol in calendar year 2020 and up to the date of the inspection on July 8, 2021. Findings include: 1. During a tour of the laboratory on 07/08/21 at approximately 9:00 AM, the inspector noted one (1) Unico centrifuge in use for urine microscopy sediment specimen processing. 2. Review of the laboratory's online procedures revealed a Urine Sediment Examination protocol that stated "Centrifuge urine at 2000 RPM for 5 minutes". 3. Review of the laboratory's centrifuge

maintenance documentation (timeframe January 1, 2020 to July 8, 2021) revealed one (1) report by QuadMedical Biomed dated 03/25/21 with the Unico centrifuge speed verified at 3202. The inspector requested to review centrifugation function check for the slower RPM per the urinalysis examination protocol. No record of verification of the 2000 RPM was available for review. 4. In an exit interview with the Senior Health Services Manager at approximately 1:30 PM, the above findings were confirmed.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policy and procedure manual, monthly quality control (QC), and an interview, the laboratory director (LD) failed to ensure that the quality assurance (QA) policies were maintained for six (6) of the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's online policy and procedure manual revealed a QA protocol (titled: Supervisor Review of Quality Control) that stated: "Monthly Quality Control Review reports for the Chemistry, Hematology, Urinalysis and Sedimentation Rate analyzers MUST be reviewed by the assigned Laboratory Director for the clinic location and signed. Complete reviews with Laboratory Director and obtain signature on Laboratory Director Form before returning documentation to the laboratory location by each 20-24 day of the month." 2. The inspector reviewed the following analyzers' monthly QC reports (July 2019 to 7/8/21): Abbott Architect c4000/i1000sr (for analytes Follicle Stimulating Hormone FSH, Testosterone, Cholesterol, Magnesium, Vitamin B12, C Reactive Protein, Potassium, and Hepatitis C Virus Antibody); Abbott Cell Dyn Emerald (for Complete Blood Count CBC parameters White Blood Cell, Red Blood Cell, Platelet, Hemoglobin); Excyte Mini Automated Erythrocyte Sedimentation Rate; and Alere Triage Meter (Myoglobin, B-Type Natriuretic Peptide BNP, Troponin-1). The review revealed that monthly QC reports were not reviewed by the lab director in the following months: Calendar year 2020: October, November, and December, Calendar year 2021: January, February, and March. The inspector inquired regarding the lapse in lab director review outlined above. The Senior Health Services Manager stated at approximately 1:00 PM: "We were experiencing staff changes during that timeframe". 3. An exit interview Senior Health Services Manager at approximately 1:30 PM confirmed the above findings.