

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0993431	(X3) Date Survey Completed 05/01/2020
Name of Provider or Supplier Hospital For Extended Recovery	Street Address, City, State 600 Gresham Drive - Suite 700, Norfolk, 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 unannounced off-site CLIA proficiency test desk review was conducted for Hospital for Extended Recovery on May 1, 2020 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:
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on an off-site desk review of the laboratory's College of American Pathologists' proficiency testing (PT) records and interviews, the laboratory failed to attain a score of at least eighty percent of acceptable responses for Chloride, Potassium, Sodium, Hematocrit, and Hemoglobin in two consecutive Chemistry and Hematology testing</p>

events resulting in unsuccessful PT performance (reviewed: 2019 Third Event, 2020 First Event). See D2097 and D2131.

D2097

ROUTINE CHEMISTRY

CFR(s): 493.841(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on an off-site desk review of proficiency testing (PT) results and interviews, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable analyte responses for Chloride (Cl), Potassium (K), and Sodium (Na) on two (2) consecutive chemistry testing events reviewed (2019 Third Event, 2020 First Event). Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) Chemistry Critical Care Aqueous PT module results, revealed analyte scores of less than 80% for the following consecutive events: CAP AQI 2019 Event 3: Chemistry specialty score 33% (unsatisfactory): analytes Cl, Creatine, Glucose, K, Na, and Urea Nitrogen all scored 0% for challenge samples AQI-11 through AQI-15 (with comment "identified by CAP as being tested and scored zero due to lack of response"); CAP AQI 2020 Event 1: Chemistry specialty score 50% (unsatisfactory): analytes Cl, K, and Na scored 0% for challenge samples AQI-01 through AQI-05 (with comment "identified by CAP as being tested and scored zero due to lack of response"); resulting in an unsuccessful Chemistry PT performance. 2. In email correspondence interviews with the technical consultant on 05/01/20 at approximately 3:00 and 3:45 PM, the above findings were confirmed.

D2131

HEMATOLOGY

CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on an off-site desk review of proficiency testing (PT) records (2019 Third Event, 2020 First Event) and interviews, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for Hemoglobin (HGB) and Hematocrit (HCT) on two (2) consecutive hematology events reviewed, resulting in unsuccessful PT performance. Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) Hematology AQI module records revealed scores of less than 80% for the following consecutive events: CAP 2019 Event 3: Hematology specialty score 0% (unsatisfactory); HGB and HCT scored 0%; sample challenges AQI-C #11 through 15 reported with comment "identified by CAP as being tested and scored zero due to lack of response"; CAP 2020 Event 1: Hematology specialty score 0% (unsatisfactory); HGB and HCT scored 0%; sample challenges AQI-A #01 through 05 reported with comment "identified by CAP as being tested and scored zero due to lack of response"; resulting in an unsuccessful PT Hematology performance. 2. In email correspondence interviews with the technical consultant on 05/01/20 at approximately 3:00 and 3:45 PM, the above findings were confirmed.