

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0520406	(X3) Date Survey Completed 03/10/2021
Name of Provider or Supplier Power County Hospital District	Street Address, City, State 510 Roosevelt St, American Falls, ID	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a random review of the maintenance log, laboratory policies and procedures and an interview with the laboratory manager on 3/10/2021, the laboratory failed to perform and document maintenance with the frequency defined by the manufacturer. The findings include: 1. A random review of the laboratory maintenance log identified the laboratory failed to perform and document maintenance as required by instrument manufacturers and laboratory policies and procedures. Microscope cleaning not documented on weeks 1 and 2 of September 2020 Siemens Dimension weekly maintenance: Clean HM probe not documented on week 1 of September and weeks 1 and 2 of December 2020 Clean R2 reagent probe not documented on week 1 of September and weeks 1 and 2 of December 2020 Siemens Dimension monthly maintenance: Clean R2 drain not documented in September and December of 2020 Stylet HM wash probes not documented in September and December of 2020 Siemens CA 500 monthly maintenance: Clean rinse bottle not documented in September and December of 2020 Replace reagent bottles not documented in September and December of 2020 Clinifuge cleaning not documented weeks 1 and 2 of December 2020 Serofuge 200 cleaning not documented weeks 1 and 2 of December 2020 2. An interview with the laboratory manager on 3/10/2021 at 11:55 am confirmed that the laboratory is not document maintenance as required by instrument manufacturers and laboratory policies and procedures. 3. The laboratory reports performing 62,325 tests annually.</p>
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 a record review and an interview with the laboratory manager on 3/10/2021, the laboratory failed to check each lot of media for its ability to support growth and/or inhibit growth. The findings include: 1. A review of media invoices that came with media received from Portneuf Medical Center identified that the laboratory failed to perform and document quality control (QC) to show the ability of the media to support growth on MacConkey Agar lot number 225065 (Remel), Columbia CNA w /5% Sheep Blood Agar lot number 231732 (Remel), Blood Agar, 5% Sheep Blood Agar lot number 225037 (Remel) and Chocolate Agar lot number 222041 (Remel). 2. A review of media invoices that came with media received from Portneuf Medical Center identified that the laboratory failed to perform and document QC to show the ability of the media to inhibit growth of gram positive organisms on MacConkey Agar lot number 225065 (Remel), 3. An interview with the laboratory manager on 3/10 /2021 at 4:40 pm confirmed that the laboratory failed to perform and document QC on media since discontinuing the performance of gram stains in June 2020.

D5555

IMMUNOHEMATOLOGY

CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory maintenance log, policies and procedure and an interview with the laboratory manager on 3/10/2021, the laboratory failed to document inspection of the audible alarm system for the blood product storage refrigerator. The findings include: 1. A random review of maintenance logs from 2019 and 2020 identified that the laboratory failed to document inspection of the audible alarm for the blood product storage refrigerator monthly as required by laboratory policy in September 2020 and December of 2020. 2. An interview with the laboratory manager on 3/10/2021 at 12:00 pm confirmed that the laboratory failed to document inspection of the audible alarm system for the blood product storage refrigerator monthly. 3. This is a repeat deficiency from the 10/22/2018 survey.