

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0977077	(X3) Date Survey Completed 08/09/2022
Name of Provider or Supplier Idaho Urologic Institute	Street Address, City, State 2855 E Magic View Dr, Meridian, 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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's Microscan individualized quality control plan (IQCP), the manufacturer instructions for use (IFU), the laboratory's Microscan quality control (QC) records, and an interview with testing personnel 1 (TP1) on 8/9 /2022, the laboratory failed to perform QC with the frequency and control organisms specified by the manufacturer. The findings include: 1. The laboratory Microscan IQCP states they will follow manufacturers IFU. The manufacturers IFU's are as follows: Positive combo panel type 44 (PC44) new lot/shipment organisms: S. aureus 29213, E. faecalis 29212, S. gallolyticus 49147, M. luteus 49732, S. saprophyticus 49907, S. xylosum 49148, S. pneumoniae 49136, E. raffinosus 49464 and weekly organisms: S. gallolyticus 49147, E. Faecalis 29212 and S. aureus 29213. Negative combo panel type 73 (NUC73) new lot/shipment organisms: E. coli 25922, P. aeruginosa 27853, K. oxytoca 49131, P. vulgaris 49132, P. stuartii 49809, P. putida 49128, S. halitotis 49138, E. faecalis 29212, S. aureus 29213, R. insidiosa 49129, E. coli 35218, K. pneumoniae 700603 and weekly organisms: E. coli 25922, P. aeruginosa 27853, E. coli 35218 and K. pneumoniae 700603. 2. A review of the laboratory Microscan QC records identified that the laboratory failed to perform new lot/shipment QC using the following organisms on PC44 panels: M. luteus 49732, S.</p>

saprophyticus 49907, S. xylosus 49148, S. pneumoniae 49136, E. raffinosus 49464 and the following organisms on NUC73 panels: K. oxytoca 49131, P. vulgaris 49132, P. stuartii 49809, P. putida 49128, S. halitosis 49138, E. faecalis 29212, S. aureus 29213, R. insidiosa 49129, E. coli 35218, K. pneumoniae 700603. 3. A review of the laboratory Microscan QC records identified that the laboratory failed to perform the required weekly QC for PC44 and NUC73 panels. 4. An interview with the laboratory TP1 on 8/9/2022 at 8:59 confirmed that the laboratory failed to test all required organisms on the two Microscan panels for new lot/shipment and they they failed to perform weekly QC. 5. The laboratory reports performing 20,000 microbiology tests annually.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on a random review of temperature logs and an interview with testing personnel 1 (TP1) on 8/9/2022, the laboratory failed to document corrective actions when sample and reagent storage temperatures were outside of the established ranges for the microbiology refrigerator. The findings include: 1. A random review of laboratory temperature logs identified that the laboratory failed to document corrective actions for the microbiology refrigerator used to store patient samples, testing media and reagents when it was not within the established range of 2-8 C for six (6) of 21 days in January 2022, four (4) of 20 days in February 2022, seven (7) of 23 days in March 2022 and four (4) of 21 days in April 2022. 2. An interview with TP1 on 8/9/2022 at 9:38 am confirmed that the laboratory had not documented corrective actions for the out of range temperatures. 3. The laboratory reports performing 20,000 microbiology tests annually.