

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2168886	(X3) Date Survey Completed 12/15/2020
Name of Provider or Supplier Helix Specialty Diagnostics	Street Address, City, State 11829 Dorsett Rd, Maryland Heights, MO	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation of verification of accuracy for the Quant Studio 12k Flex PCR and interview with the technical supervisor (TS), the laboratory failed to verify accuracy of eighteen of eighteen organisms twice annually. Findings: 1. Review of Quant Studio 12k Flex PCR verification of accuracy showed no documentation for the organisms acinetobacter baumannii, candida albicans, cirobacter freundii, enterobacter aerogenes, enterbacter cloacae, esherichia coli, enterobacter faecalis, enterobacter faecium, kiebsiella oxytoca, kiebsiella pneumoniae, morganelle morganii, pseudomonas aeruginosa, proteus mirabillis, providencia stuartii, proteus vulgaris, streptococcus agalactiae, staphylococcus aureus and strapylococcus saprophyticu. 2. Interview with the TS on December 15, 2020 at 11:45 AM confirmed the laboratory failed to verify the accuracy of eighteen organisms twice annually.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
Based on review of 2019/2020 temperature logs, Quant Studio 12k Flex PCR manufacturer instructions and interview with the technical supervisor (TS), the laboratory failed to monitor room temperature. Findings: 1. Review of temperature logs showed no room temperature documented in the room containing the Quant Studio 12k Flex PCR from December 11, 2019 to December 15, 2020. 2. Review of Quant Studio 12k Flex PCR manufacturer instructions states temperature range of 4-99.9 degrees Celsius required. 3. Interview with the TS on December 15, 2020 at 11:45 AM confirmed the laboratory failed to monitor room temperature.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

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--
At least once a day patient specimens are assayed or examined perform the following for--
Each qualitative procedure, include a negative and positive control material; (g)
The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of 2019/2020 Quant Studio 12k Flex PCR quality control (QC), patient reports and interview with the technical supervisor (TS), the laboratory failed to perform a positive and negative QC material each day of patient testing for 17 of 18 organisms. Findings: 1. Review of 2019/2020 Quant Studio 12k Flex PCR QC showed no documentation of QC for the organisms: acinetobacter baumannii, cirobacter freundii, enterobacter aerogenes, enterbacter cloacae, esherichia coli, enterobacter faecalis, enterobacter faecium, kiebsiella oxytoca, kiebsiella pneumoniae, morganelle morganii, pseudomonas aeruginosa, proteus mirabillis, providencia stuartii, proteus vulgaris, streptococcus agalactiae, staphylococcus aureus and strapylococcus saprophyticu. 2. Review of patient reports from December 11, 2019 to date December 15, 2020 showed 335 patients results were reported on 207 runs. 3. Interview with the TS on December 15, 2020 at 11:45 AM confirmed the laboratory failed to perform a positive and negative QC material on each organism on the Quant Studio 12k Flex PCR each day of patient testing.