Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D1027382	12/31/2020
Name of Provider or Supplier	**Street Address, City, State**	
Heartland Health Laboratories, Inc	10435 Lackman Road, Lenexa, KS	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the review of test procedures, Quality Control (QC) records, patient test records and interview, the laboratory failed to have procedures approved, signed, and dated by the current laboratory director before use. Findings: 1. Review of the Cephied Xpert Xpress SARS-CoV-2 procedure revealed the laboratory director signature dated 11/08/2020. 2. Review of the Cephied Xpert Xpress SARS-CoV-2 QC page showed results starting 6/29/2020. 3. Review of patient test records revealed the Cephied Xpert Xpress SARS-CoV-2 testing put into patient use as of 6/29/2020. 4. Review of the Cephied Xpert Xpress SARS-CoV-2/FLU/RSV procedure revealed the laboratory director signature dated 11/18/2020. 5. Review of the Cephied Xpert Xpress SARS-CoV-2/FLU/RSV QC page showed results starting 11/12/2020. 6. Review of patient test records revealed Cephied Xpert Xpress SARS-CoV-2/FLU /RSV testing put into patient use as of 11/16/2020. 7. Interview with General Supervisor #1 on December 31, 2020 at 2:35 p.m. confirmed, the laboratory failed to have procedures approved, signed, and dated by the current laboratory director before use.
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 an absence of thermometer function check protocols, function check records or current certificates of accuracy and interview, the laboratory failed to define and perform a function check protocol for the thermometers. Findings: 1. No documentation of a function check protocol for the thermometers was available at the time of survey. 1. No documentation was available for performance of function checks on 11 of 11 thermometers for a 2 year period. 2. No documentation was available for current certification of accuracy on 11 of 11 thermometers for a 2 year period. 2. Interview with the GS #1 on 12/31/2020 at 10:45 a.m. confirmed, the laboratory failed to define and perform a function check protocol for the thermometers.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, laboratory procedure, Individualized Quality Control Plan (IQCP), quality control (QC) records, laboratory test list, email and staff interview, the laboratory failed to obtain QC results that met the laboratory's and manufactures's criteria for acceptability before reporting patient test results for the Cephied Xpert Xpress SARS CoV-2 and the Cephied Xpert Xpress SARS CoV-2/Flu /RSV. Findings: 1. Review of the manufacturer instructions for the Cephied Xpert Xpress SARS CoV-2 revealed that External Controls are to be performed in accordance with federal regulations for laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform high and moderate complexity tests. One postive control and one negative control each day of patient testing per 493.1256. 2. Review of the laboratory procedure for the Cephied Xpert Xpress SARS CoV-2, signed by the laboratory director 11/08/2020, revealed Exernal QC to be performed in accordance with the laboratory's IQCP. One positive control and one negative control per each new lot and/or shipment of cartridges. 3. Review of the laboratory's IQCP for the Cephied Xpert Xpress SARS CoV-2, signed by the laboratory director 11/08/2020, revealed the risk assessment did not contain in house data from the laboratory and its testing personnel that demonstrated the stability of the test system for the frequency of the QC documented in the QCP. 4. Review of QC records for the Cephied Xpert Xpress SARS CoV-2 revealed QC was performed on 6/29/2020, 7/27/2020, 8/11/2020, 9/15/2020, 9/23 /2020, 9/30/2020, 10/2/2020, 10/15/2020, 11/5/2020 and 11/12/2020 in accordance with the IQCP plan dated 11/8/2020. QC records note the Cephied Xpert Xpress SARS-CoV-2 testing was switched to Cephied Xpert Xpress SARS CoV-2/Flu/RSV on 11/12/2020. 5. Review of CLIA Volumes 2020 test list and email from GS#1shows the SARS CoV-2 test volume to be 700 with patient testing started 6/29/2020. 6. Review of the manufacturer instructions for the Cephied Xpert Xpress SARS CoV-2

	/Flu/RSV revealed that External Controls are to be performed in accordance with federal regulations for laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform high and moderate complexity tests. One postive control and one negative control each day of patient testing per 493.1256. 7. Review of the laboratory procedure for the Cephied Xpert Xpress SARS CoV-2/Flu/RSV, signed by the laboratory director 11/18/2020, revealed Exernal QC to be performed as one positive control and one negative control per each new lot and/or shipment of cartridges. No reference to IQCP was present. 8. Review of the laboratory's IQCP for the Cephied Xpert Xpress SARS CoV-2/Flu /RSV, signed by the laboratory director 11/18/2020, revealed the risk assessment did not contain in house data from the laboratory and its testing personnel that demonstrated the stability of the test system for the frequency of the QC documented in the QCP. 9. Review of QC records for the Cephied Xpert Xpress SARS CoV-2/Flu /RSV revealed QC was performed on 11/12/2020, 11/18/2020, 12/8/2020, 12/15 /2020, 12/22/2020 and 12/31/2020. 10. Review of CLIA Volumes 2020 test list and email from GS#1shows the SARS CoV-2/Flu/RSV test volume to be 860 (215 test cartridges x 4 tests) with patient testing started 11/16/2020. 11. Interview with GS #1 on 12/31/2020 at 2:30 p.m. confirmed, the laboratory failed to obtain QC results that met the laboratory's and manufactures's criteria for acceptability before reporting patient test results for the Cephied Xpert Xpress SARS CoV-2 and the Cephied Xpert Xpress SARS CoV-2/Flu/RSV.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of quality control (QC) records, test procedures and IQCP for the Cephied Xpert Xpress SARS CoV-2 and SARVS CoV-2/Flu/RSV and interview, the laboratory director fails to ensure the establishment of a QC program that meets the CLIA requirements (see D5481).
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on the review of instrument validation record and interview, the laboratory director failed to ensure the establishment of acceptable levels of analytical

	performance of the Microscan instrument before use in patient testing. 1. Review of insturment validation records for the Microscan Instrument S/N 49610195 performed June 2020 and place into use for patient testing on July 1, 2020 reveals no approval documentation from the laboratory director. 2. Interview with the GS#1 12/31/2020 at 2 p.m. confirmed, the laboratory director failed to ensure the establishment of acceptable levels of analytical performance of the Microscan instrument before use in patient testing.