Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2175316	09/30/2020
Name of Provider or Supplier	**Street Address, City, State**	
Infinity Health	219 W Washington Street, Osceola, IA	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report), at approximately 11:00 am on 09/30/2020, the laboratory failed to have a written procedure defining the criteria for referral or review of abnormal complete blood count (CBC) differentials.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: A. Based on review of the laboratory's refrigerator temperature records and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 11:15 am on 09/30/2020, the laboratory failed to take and document corrective action when the laboratory refrigerator temperatures fell outside the acceptable range for 10 out of 31 days of patient testing in March 2020. The findings include: 1. The laboratory stored the CELL-DYN Emerald complete blood count (CBC) quality controls in the laboratory refrigerator. 2. The refrigerator temperature log listed the acceptable temperature range as 35.6- 46.4 degrees Fahrenheit. 3. The laboratory documented the following unacceptable refrigerator temperatures (degrees Fahrenheit): 03/02/20- 34.3; 03/05/20- 35.4; 03/11/20- 26.8; 03/13/20- 26.8; 03/14 /20- 27.9; 03/15/20- 27.1; 03/16/20- 29.1; 03/17/20- 20.7; 03/18/20- 22.6; and 03/19 /20- 23.4. 4. At the time of the survey, personnel identifier #6 confirmed that the laboratory did not perform or document corrective action when the refrigerator temperatures fell outside the acceptable range on the previously listed dates. B. Based on review of patient test records, the CELL-DYN Emerald operator's guide, and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 09/30/2020, the laboratory failed to perform and document corrective action when hematology equipment failed to meet the laboratory's established operating parameters for two out of four patient test reports (patient identifiers C and D) reviewed from March 2020. The findings include: 1. Patient identifiers C and D had complete blood counts (CBC) and differentials performed on 03/17/2020. 2. For patients C and D, the following test results were flagged with an asterisk (*): white blood cell (WBC), absolute lymphocyte cell count (LYM), absolute mid-sized cell count (MID), absolute granulocyte cell count (GRA), lymphocyte cell percentage (LYM%), mid-sized cell percentage (MID%), and granulocyte cell percentage (GRA%). 3. Review of the CELL-DYN Emerald operator's guide revealed that test results flagged with an asterisk indicate that the instrument failed to meet established operating parameters and requires additional action be taken as specified by the manufacturer or the laboratory's review criteria. 4. At the time of the survey, laboratory personnel identifier #6 confirmed that additional action had not been taken for CBC test results flagged with asterisks for patient identifiers C and D.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to

	network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test reports, instrument result printouts and confirmed by laboratory personnel identifier #6 (refer to Laboratory Personnel Report) at approximately 11:00 am on 09/30/2020, the laboratory failed to have a system in place to ensure manually transcribed test results are accurately and reliably sent from the point of data entry to final report destination for one out of four complete blood count (CBC) test reports reviewed. The findings include: 1. Patient B had a CBC performed on 03/20/2020 with a mean corpuscular volume (MCV) of 98.7 fL. 2. Testing personnel entered the MCV result of 96.7 fL into the electronic health record (EHR). 3. Laboratory personnel identifier #6 confirmed the patient test report was not accurate and the MCV result should have been 96.7 fL.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's "Quality Assessment of Lab Practices" policy, lack of quality assessment records and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 09/30/2020, the laboratory director failed to ensure that the laboratory maintained the quarterly quality assessment (QA) activities established in the laboratory's policy for three out of three time periods from 01/01/2020- 09/30/2020. The findings include: 1. The laboratory's "Quality Assessment of Lab Practices" policy stated that the following would be reviewed on a quarterly basis: *Controls on equipment tested and within acceptable limits *Calibration performed and acceptable, done according to manufacturer's recommendation *Maintenance performed and acceptable *Function checks performed and acceptable *Refrigerator/room/freezer temperature recorded and acceptable 2. At the time of the survey, the laboratory did not have documentation showing it had reviewed the above activities from 01/01/2020- 09/30/2020.