Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0382881	09/30/2020
Name of Provider or Supplier	**Street Address, City, State**	
Infinity Health	802 East Ackerly Street, Lamoni, 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 #4 (refer to the Laboratory Personnel Report), at approximately 3: 30 pm on 09/30/2020, the laboratory failed to have the following written procedures: criteria for referral or review of abnormal complete blood count (CBC) differentials and post vasectomy semen analysis.
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 review of hematology quality control (QC) records and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 09/30/2020, the laboratory failed to ensure that results of control materials met the laboratory's and manufacturer's test system criteria for acceptability before reporting patient test results for 2 out of 22 days of patient testing (03/19/2020 and 03/24/2020) in March 2020. Refer to D5783 for findings.
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: Based on review of patient test records, the CELL-DYN Emerald operator's guide, and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 2:30 pm 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 three out of three patient test reports (patient identifiers A, B and C) reviewed from March 2020. The findings include: 1. Patient A had a complete blood count (CBC) and differential performed on 03/31/2020. 2. Patient B had a CBC and differential performed on 03/24/2020. 3. Patient C had a CBC and differential performed on 03/19/2020. 4. For patients A, B and C, the following test results were flagged with a "s": 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%). 5. Review of the CELL-DYN Emerald operator's guide revealed that test results flagged with a "s" 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 #4 confirmed that additional action had not been taken for CBC test results flagged with a "s" for patient identifiers A, B and C.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken

	when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of hematology quality control (QC) records and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 09/30/2020, the laboratory failed to take and document corrective action when the hematology QC failed to meet the laboratory's established criteria for two out of 22 days of patient testing (03/19/2020 and 03/24/2020) in March 2020. The findings include: 1. For CELL-DYN hematology QC lot number N9350, the acceptable ranges for the following analytes were listed: *Red blood cell (RBC): 3.85- 4.35 x10^6/uL *Hemoglobin (HGB): 10.7- 12.1 g/dL *Platelet (PLT): 159- 229 x10^3/uL 2. On 03/19/2020, the laboratory recorded the following QC results for lot N9350: RBC- 3.73 x10^6/uL and PLT- 158 x10^3/uL. 3. On 03/24 /2020, the laboratory recorded the following QC results for lot N9350: RBC- 3.82 x10^6/uL and 10.5 g/dL. 4. For CELL-DYN hematology QC lot number H9350, the acceptable ranges for the following analytes were listed: *Red blood cell (RBC): 4.77- 5.37 x10^6/uL *Hemoglobin (HGB): 14.1- 16.1 g/dL 5. On 03/19/2020, the laboratory recorded the following QC result for lot H9350: RBC- 4.73 x10^6/uL. 6. On 03/24/2020, the laboratory recorded the following QC results for lot H9350: RBC- 4.64 x10^6/uL and 14.0 g/dL. 7. The laboratory performed complete blood counts (including RBC, HGB, and PLT testing) on 03/19/2020 for 6 patients and on 03/24 /2020 for 5 patients. 3. At the time of the survey, the laboratory did not have corrective action for the out of range QC on 03/19/2020 or 03/24/2020.
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 #4 (refer to Laboratory Personnel Report) at approximately 2:45 pm 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 three complete blood count (CBC) test reports reviewed. The findings include: 1. Patient C had a CBC performed on 03/19/2020 with a hematocrit level of 28.3%. 2. Testing personnel entered the

	hematocrit level of 29.3% into the electronic health record (EHR). 3. Laboratory personnel identifier #4 confirmed the patient test report was not accurate and the hematocrit level should have been 28.3%.
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 #4 (refer to the Laboratory Personnel Report) at approximately 4:00 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 11 out of 11 time periods from 01/01/2018- 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 01/01/2018- 09/30/2020.