

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D2185613	<b>(X3) Date Survey Completed</b>  10/02/2020
<b>Name of Provider or Supplier</b>  Herrons Holdings	<b>Street Address, City, State</b>  628 Nile Kinnick Drive S, Adel, IA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on lack of test kit records, the COVID-19 IgG/IgM Rapid Test Cassette manufacturer's package insert, and interview with the laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 9/30/2020, the laboratory failed to retain records of the lot number and expiration dates for 25 out of 26 boxes of COVID-19 IgG/IgM Rapid Test Cassettes. The findings include: 1. The laboratory began performing patient testing on 6/8/2020 using the COVID-19 IgG /IgM Rapid Test Cassette manufactured by Zhejiang Orient Gene Biotech Co, LTD. 2. From 6/8/2020 - 9/30/2020 the laboratory performed testing on 635 patients using the COVID-19 IgG/IgM Rapid Test Cassette test system. 3. The manufacturer's package insert stated that each box contained 25 sealed pouches (each containing a test cassette, dropper, and desiccant.) 4. The laboratory used 26 boxes of test kits to perform testing on 635 patients. 5. The laboratory only had the lot number and expiration date for the current box of test kit (lot 2004158).</p>
<b>D5014</b>	<p><b>GENERAL IMMUNOLOGY</b> CFR(s): 493.1208</p> <p>If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p>

This CONDITION is not met as evidenced by:  
 Based on observations made during the survey, review of the COVID-19 IgG/IgM Rapid Test Cassette manufacturer's package insert, lack of quality control and temperature records, patient test records, and interview with laboratory personnel identifier #1 (refer to the Laboratory Test Report), the laboratory failed to meet the general immunology requirements for: establishing procedures as specified in D5403; ensuring the procedure manual is approved, signed, and dated by the laboratory director as specified in D5047; documenting temperatures as specified in D5413; establishing performance specifications as specified in D5423; performing positive and negative quality controls as specified in D5449; ensuring test reports meet requirements as specified in D5805.

**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 COVID-19 IgG/IgM Rapid Test Cassette manufacturer's package insert and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 9/30/2020, the laboratory failed to have a procedure manual which included: requirements for specimen collection, specimen processing, criteria for specimen acceptability and rejection; control procedures; corrective action when control results fail to meet the laboratory's criteria for acceptability; laboratory's system for entering results in the patient record; and the course of action to take if a test system becomes inoperable. The findings include: 1. The laboratory used the COVID-19 IgG/IgM Rapid Test Cassette manufacturer's package insert as the procedure for performing COVID antibody testing. 2. The manufacturer's package insert did not include the above procedures. 3. From 6/8/2020 - 9/30/2020 the laboratory performed testing on 635 patients using the COVID-19 IgG/IgM Rapid Test Cassette test system. 4. At the time of the survey, the laboratory did not have additional laboratory procedures.

**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 review of the COVID-19 IgG/IgM Rapid Test Cassette manufacturer's package insert and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 9/30/20, the laboratory failed to have the laboratory director approve, sign and date the procedure for performing COVID antibody testing. The findings include: 1. The laboratory used the COVID-19 IgG/IgM Rapid Test Cassette manufacturer's package insert as the procedure for performing COVID antibody testing. 2. The laboratory director did not approve, sign or date the procedure. 3. From 6/8/2020 - 9/30/2020 the laboratory performed testing on 635 patients using the COVID-19 IgG/IgM Rapid Test Cassette test system.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:

Based on lack of temperature records, observations made during the survey, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:00 on 9/30/2020, the laboratory failed to document the daily temperature to ensure the proper storage of reagents and test kits for 115 out of 115 days from 6/8/2020 - 9/30/2020. The findings include: 1. The laboratory began performing patient testing on 6/8/2020 using the COVID-19 IgG/IgM Rapid Test Cassette manufactured by Zhejiang Orient Gene Biotech Co, LTD. 2. The package insert states, "The kit can be stored at room temperature or refrigerated (2 - 30 degrees Celsius/36 - 86 degrees Fahrenheit)." 3. The laboratory stored the COVID-19 IgG /IgM Rapid Test Cassettes at the front of the laboratory next to a door leading to the outside and next to a window. 4. The laboratory did not have temperature records from 6/8/2020 - 9/30/2020.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test

results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:  
Based on review of the COVID-19 IgG/IgM Rapid Test Cassette manufacturer's package insert and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 9/30/2020, the laboratory failed to establish the performance specifications of accuracy, precision, analytical sensitivity, and analytical specificity. The findings include: 1. The laboratory began performing patient testing on 6/8/2020 using the COVID-19 IgG/IgM Rapid Test Cassette manufactured by Zhejiang Orient Gene Biotech Co, LTD. 2. From 6/8/2020 - 9/30/2020 the laboratory performed testing on 635 patients using the COVID-19 IgG /IgM Rapid Test Cassette. 3. The manufacturer's package insert stated, "This test has not been reviewed by the FDA." 4. The laboratory did not establish the performance specifications of accuracy, precision, analytical sensitivity, and analytical specificity.

**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 lack of quality control records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 9 /30/2020, the laboratory failed to perform a positive and negative quality control each day of patient testing for 68 out of 68 days from 6/8/2020 - 9/30/2020. The findings include: 1. The laboratory began performing patient testing on 6/8/2020 using the COVID-19 IgG/IgM Rapid Test Cassette manufactured by Zhejiang Orient Gene Biotech Co, LTD. 2. The laboratory performed patient testing on the following dates: 6 /8 - 6/13/2020; 6/15 - 6/20/2020; 6/22 - 6/27/2020; 6/29 - 7/3/2020; 7/6 - 7/11/2020; 7 /13 - 7/18/2020; 7/20 - 7/25/2020; 7/27 - 8/1/2020; 8/3 - 8/8/2020; 8/10 - 8/15/2020; 8 /17/2020; 8/19/2020; 8/21 - 8/22/2020; 8/24 - 8/29/2020 and 8/31/2020. 3. During this time period the laboratory performed testing on 635 patients using the COVID-19 IgG /IgM Rapid Test Cassette. 4. The laboratory did not perform a positive and negative control for any of the dates listed.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on review of a patient test report and interview with the laboratory personnel, identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 9/30/2020, the laboratory failed to include the address of the testing facility for one out of one patient test report (patient identifier #1) from 6/10/20. The findings include: 1. The laboratory began performing patient testing on 6/8/2020 using the COVID-19 IgG/IgM Rapid Test Cassette manufactured by Zhejiang Orient Gene Biotech Co, LTD. 2. Patient identifier #1 had COVID-19 IgG/IgM testing performed on 6/10/2020. 3. The patient test report did not contain the address of the testing facility.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on observations made during the survey, review of the COVID-19 IgG/IgM Rapid Test Cassette manufacturer's package insert and Laboratory Personnel Report (CMS-209), lack of quality control and temperature records, patient test records, and interview with laboratory personnel identifier #1 (refer to the Laboratory Test Report), the laboratory director failed to meet responsibility requirements including: establishing performance verification procedures as specified in D6086; ensuring a quality control program is established and maintained as specified in D6093; ensuring a quality assessment program is established and maintained as specified in D6094; and ensuring an approved procedure manual is available to all personnel as specified in D6106.

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:  
Based on review of the COVID-19 IgG/IgM Rapid Test Cassette manufacturer's package insert and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 9/30/2020, the laboratory director failed to establish the performance specifications of accuracy, precision, analytical sensitivity, and analytical specificity. Refer to D5423.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	<p>This STANDARD is not met as evidenced by:  Based on lack of quality control records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 9/30/2020, the laboratory director failed to ensure the laboratory maintained a quality control program to perform a positive and negative quality control each day of patient testing for 68 out of 68 days from 6/8/2020 - 9/30/2020. Refer to D5449.</p>
<p><b>D6094</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by:  Based on lack of a procedure manual and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 9/30/2020, the laboratory director failed to ensure that the laboratory established and maintained a quality assessment program that included the four quality systems: general laboratory, pre analytical, analytical, and post analytical.</p>
<p><b>D6106</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by:  Based on review of the COVID-19 IgG/IgM Rapid Test Cassette manufacturer's package insert and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:30 PM on 9/30/2020, the laboratory director failed to ensure the laboratory had an approved procedure manual. Refer to D5403 and D5407.</p>