| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 23D2162722 | 02/22/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Integrated Research Diagnostics | 6135 Woodward Avenue Room 2221, Detroit, MI | |

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 |
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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the Laboratory Director, Clinical Consultant, and the Testing Personnel, the laboratory failed to follow its established policy to assess competency of personnel serving as clinical consultant and technical consultant for 2 (February 2021 to February 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Personnel Competency Policy/Procedure" revealed a section stating, "All testing personnel, Director, Technical Supervisor and General Supervisor must be reviewed for their ability to perform their jobs correctly. Laboratory compliance requires personnel to be reviewed to ensure all personnel have the appropriate training, education and experience for the type of testing being performed. Documentation of the personnel's education must be on file for all Laboratory Personnel. Laboratory compliance requires training/competency to be completed initially, 6 months after the original start date and annually there after." 2. The surveyor requested the competency assessments performed for personnel serving as clinical consultant and technical consultant on 2/22/23 at 8:49 am and the documentation was not made available. 3. An interview on 2/22/23 at 8:49 am with the Laboratory Director, Clinical Consultant, and the Testing Personnel confirmed the laboratory had not performed competency assessments for personnel serving as clinical consultant and technical consultant. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b) |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the Laboratory Director, Clinical Consultant, and the Testing Personnel, the laboratory failed to include in its procedure for testing using the Sysmex XN-430 hematology analyzer the patient reference intervals for 2 (February 2021 to February 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Sysmex XN-450/XN-430 CLSI Procedure" revealed a lack of patient reference intervals. 2. An interview on 2/22/23 at 9:08 am with the Laboratory Director, Clinical Consultant, and the Testing Personnel confirmed the laboratory had not established patient reference intervals and they had not been present in the laboratory's test procedure. |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation and interview with the Testing Personnel, the laboratory failed to label its hematology controls to reflect the expiration date once the controls were opened for 6 of 6 quality control specimens observed. Findings include: 1. The surveyor observed 6 XN-L Check hematology quality control specimens in the refrigerator on 2/22/23 at 8:11 am that had been opened and did not indicate the updated expiration date to reflect the stability once opened: a. Lot number 23221401 Level 1 b. Lot number 23221402 Level 2 c. Lot number 23221403 Level 3 d. Lot number 30411401 Level 1 e. Lot number 30411402 Level 2 f. Lot number 30411403 Level 3 2. A review of the laboratory's "XN-L Check Hematology Control for Sysmex XN-L analyzers" manufacturer's document revealed a section stating, "Open vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2-8 degrees C after being re-capped." 3. An interview on 2/22/23 at 8:14 am |

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| | with the Testing Personnel confirmed the quality control specimens did not have the expiration date reflecting the stability when opened. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the Laboratory Director, Clinical Consultant, and Testing Personnel, the laboratory failed to ensure patient test reports included at least two patient identifiers and the name of the laboratory for 3 (Patients 03F001, 03F002, and 03F002) of 3 patients tested by the laboratory. Findings include: 1. A review of patient test reports revealed a lack of a second patient identifier and laboratory name on the following patient test reports from March 2021 to February 2023: a. Patient 03F001 with the test report date of 2/15/21. b. Patient 03F002 with the test report date of 3/16/21. c. Patient 03F002 with the test report date of 6/16/21. 2. A review of the laboratory's "Test Report" policy revealed a section stating, "The patients test report must indicate the following: 1. The patients name and a unique identifier. 2. The name and address of all laboratory locations where tests may be performed. 3. The date and time the sample was drawn and the date the test was performed. 4. The test performed. 5. The test result with units of measurement. 6. The initials of the person performing the test." 3. An interview on 2/22/23 at 9:04 am with the Laboratory Director, Clinical Consultant, and Testing Personnel confirmed the patients listed above lacked a second identifier and the name of the laboratory on the test reports. |
| **D6022** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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 and quality assessment programs are established and maintained to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the Testing Personnel, the Laboratory Director failed to establish a quality assessment program that included the assessment of preanalytic and postanalytic phases of the testing process for 2 (February 2021 to February 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's policies and procedures revealed a lack of policies and procedures established for the quality assessment performance. 2. A review of the laboratory's "Quality Assurance |

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| | Review Sheet" revealed a checklist that is reviewed monthly. The checklist did not contain measures for assessing quality of the preanalytic and postanalytic phases of testing. 3. An interview on 2/22/23 at 9:30 am with the Testing Personnel confirmed the laboratory had not established a quality assessment program to include preanalytic and postanalytic phases of testing. |