

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D2074775	<b>(X3) Date Survey Completed</b>  09/19/2018
<b>Name of Provider or Supplier</b>  Fall River Family Medicine	<b>Street Address, City, State</b>  21 Winn Dr, Rexburg, ID	
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>D3037</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to retain all proficiency testing documents from the American Academy of Family Physicians (AAFP) in the specialty of hematology since the last survey on July 22, 2017. Findings: 1. A review of proficiency testing (PT) results from the AAFP revealed the laboratory failed to retain the signed attestation statements, PT results and scores from AAFP, Cell-Dyn analyzer print-outs, and documents of review and corrective actions for 2017 event B and C and 2018 event A. 2. An interview on September 19, 2018 at 10:25 AM, with the laboratory lead, confirmed the laboratory failed to retain all PT documents since the last survey.</p>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to verify the accuracy of potassium hydroxide (KOH), urine sediment examination, presence or absence of semen, and ectoparasite at least twice annually since the last survey on July 22, 2017. Findings: 1. A record review revealed the laboratory failed to document the accuracy of fungal and ectoparasite, urine sediment examination, and the presence or absence of semen at least twice a year since the last</p>

survey in 2017. 2. An interview on September 19, 2018 at 10:45 AM, with the laboratory lead, confirmed the laboratory failed to document the accuracy of the microscopic examinations for fungal, ectoparasite, urine, and semen at least twice a year.

**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 a procedure manual review and an interview with the laboratory lead, the laboratory failed to include the steps to take for corrective actions when control or calibration material fails to meet the laboratory's specified requirements, reference ranges for pediatric population, panic values for the analytes, limitations in test methodology, and steps to take when the Emerald Cell-Dyn complete blood count (CBC) analyzer becomes inoperable since the last survey on July 22, 2017. Findings: 1. A review of the laboratory's procedure manual revealed the procedure failed to include pediatric reference ranges, panic values for patient CBC results, limitations in testing and reporting, corrective actions to take when quality controls or calibrations fail, and instructions to take when the Cell-Dyn analyzer becomes inoperable. 2. An interview on September 17, 2018 at 11:45 AM, with the laboratory lead, confirmed the laboratory's procedure manual failed to include all CLIA requirements for patient testing.

**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 a record review and an interview with the laboratory lead, the laboratory failed to monitor and document the temperatures for the refrigerator where external liquid quality control material for hematology testing are stored since the last survey on July 22, 2017. Findings: 1. A review of the temperature log worksheet for the laboratory refrigerator revealed the laboratory failed to document the temperatures for 23 out of 31 days in March 2018, 16 out of 30 days in April, and 18 out of 31 days in June 2018. 2. An interview on September 17, 2018 at 12:15 PM, with the laboratory lead, confirmed the laboratory failed to write the temperatures on the temperature log worksheet.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
Based on a record review and an interview with the laboratory lead, the laboratory failed to establish, perform, and document preventative maintenance activities for the Emerald Cell-Dyn hematology analyzer as specified by the manufacturer since the last service performed in January 2016. Findings: 1. A review of instrument maintenance activity logs revealed the laboratory failed to have a system in place to perform and document preventative maintenance and troubleshooting activities for the Cell-Dyn analyzer. 2. An interview on September 17, 2018 at 12:15 PM, with the laboratory lead, confirmed the laboratory failed to establish and document preventative maintenance and troubleshooting activities for the analyzer.

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:  
Based on a record review and an interview with the laboratory lead, the laboratory failed to perform and document calibration procedures at least once every 6 months or as required by the manufacturer for the Emerald Cell-Dyn hematology analyzer between January 31, 2017 and June 8, 2018. Findings: 1. A record review of calibration reports for the Cell-Dyn analyzer revealed the laboratory failed to perform and document calibration activities at least once every 6 months or as recommended

by the manufacturer. 2. An interview on September 17, 2018 at 12:45 PM, with the laboratory lead, confirmed the laboratory failed to perform and document calibration procedure activities.

**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 quality control records and an interview with the laboratory lead, the laboratory failed to meet the manufacturer's quality control reference criteria prior to reporting 36 patient test results during May 2018. Findings: 1. A review of quality control records from May 1, 2018 through May 28, 2018 revealed 2 out of 3 levels of Cell-Dyn 18Plus Controls failed to meet the manufacturer's reference ranges for 9 out of 13 days, and 4 out of 13 days revealed 3 out of 3 levels of controls failed to meet the manufacturer's reference ranges prior to reporting 36 patients. 2. An interview on September 17, 2018 at 12:35 PM, with the laboratory lead, confirmed the laboratory failed to meet the manufacturer's quality control reference criteria prior to reporting patient results.

**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 records review and an interview with the laboratory lead, the laboratory failed to document corrective actions for the hematology analyzer to include quality control storage and testing, calibration performance, and patient testing and reporting since the last survey on July 22, 2017. Findings: 1. A record review of the refrigerator temperature log for the laboratory revealed the laboratory failed to document corrective actions when the refrigerator was not within the laboratory's established temperature range during the months on April, May, and June of 2018. 2. A review of the quality controls for the Emerald Cell-Dyn hematology analyzer revealed the laboratory testing personnel failed to document corrective action activities when the Cell-Dyn 18Plus Controls failed to meet the manufacturer's reference range. 3. A review of a calibration performed for the Emerald Cell-Dyn hematology analyzer on May 9, 2018 revealed the laboratory failed to document the corrective actions when the calibration failed to meet the instrument specifications. 4. An interview on September 17, 2018 at 1:15 PM, with the laboratory lead, confirmed the laboratory

	<p>failed to perform and document corrective actions when calibration and quality control materials failed acceptability requirements.</p>
<p><b>D5787</b></p>	<p><b>TEST RECORDS</b> CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to record the identity of the testing personnel who performed complete blood counts (CBCs) on the Emerald Cell-Dyn hematology analyzer since the last survey on July 22, 2017. Findings: 1. A review of patient result records during May 2018 revealed the identity of the testing personnel who performed CBCs on patient samples was not recorded. 2. An interview on September 17, 2018 at 1:00 PM with the laboratory lead, confirmed the identity of the laboratory testing personnel who performed the patient tests was not recorded.</p>
<p><b>D6020</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on records review and an interview with the laboratory lead, the laboratory director failed to ensure the quality control program for the Emerald Cell-Dyn hematology analyzer meets the CLIA requirements since the last survey on July 22, 2017. Findings: 1. A review of quality control records from the Emerald Cell-Dyn hematology analyzer revealed the laboratory director failed to assure a quality control program was established to detect failures, errors in operator performance, and monitoring the test system over time. 2. An interview on September 17, 2018 at 1:10 PM with the laboratory lead, confirmed the laboratory director failed to assure the quality control activities for the hematology analyzer meet CLIA regulations and manufacturer requirements.</p>
<p><b>D6021</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>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</p>

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 records review and an interview with the laboratory lead, the laboratory director failed to assure the quality assessment program for the Emerald Cell-Dyn hematology test system meets the CLIA requirements since the last survey on September 28, 2016. Findings: 1. A review of documents in the laboratory for corrective actions and troubleshooting revealed the laboratory director failed to identify and correct problems in the hematology complete blood count test system. 2. An interview on September 17, 2018 at 1:10 PM with the laboratory lead, confirmed the laboratory director failed to identify, document, and correct problems in analytic system for the CBC testing on the Cell-Dyn analyzer.

**D6025**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(7)

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)(7) Ensure that patient test results are reported only when the system is functioning properly.

This STANDARD is not met as evidenced by:

Based on a review of quality control records and an interview with the laboratory lead, the laboratory director failed to assure that patient complete blood count (CBCs) results were reported only when the system was functioning properly from March 27, 2018 through June 11, 2018. Findings: 1. A review of quality control records revealed the laboratory failed to meet the quality control requirements for the Emerald Cell-Dyn hematology analyzer prior to reporting patient CBC results. See D5481. 2. A review of calibration data for the Emerald Cell-Dyn hematology analyzer on May 9, 2018, revealed the laboratory failed to troubleshoot and document procedures for the failed calibration prior to reporting patient CBC results. See D5437. 3. An interview on September 17, 2018 at 1:10 PM with the laboratory lead, confirmed the laboratory director failed to report patient CBCs only when the test system is functioning properly.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on a record review and an interview with the laboratory lead, the laboratory director failed to ensure testing personnel receive appropriate training, education, and demonstrate they can perform testing on the Emerald Cell-Dyn hematology analyzer prior to testing patient complete blood count (CBCs) samples since hire dates in 2017 and 2018. Findings: 1. A record review revealed 4 out of 14 testing personnel failed to have documented records of training for the Cell-Dyn hematology analyzer prior to testing patient CBC samples since their hire dates in 2017 and 2018. 2. An interview on September 19, 2018 at 10:35 AM, with the laboratory lead, confirmed the laboratory director failed to ensure the testing personnel receive the appropriate training, education, and demonstrate they can reliably perform testing for patient CBCs.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on a record review and an interview with the laboratory lead, the technical consultant failed to evaluate the competency for testing personnel performing complete blood counts (CBCs), microscopic examinations for urine sediment, potassium hydroxide (KOH), ectoparasites, and post-vasectomy semen analysis since the last survey the last survey on July 22, 2017. Findings: 1. A review of personnel documents revealed the technical consultant failed to evaluate the competency for 14 out of 14 testing personnel performing CBCs, microscopic examinations for urine sediment, KOH, ectoparasites, and post-vasectomy semen analysis since the last survey. 2. An interview on September 19, 2018 at 10:45 AM, with the laboratory lead, confirmed the technical consultant failed to assess and document the competency for the 14 testing personnel.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on record reviews of personnel documents and an interview with the laboratory lead, the technical consultant failed to assess employee competency at least semiannually during their first year of patient testing on the Emerald Cell-Dyn hematology analyzer used to test complete blood counts (CBCs) since July 22, 2017. Findings: 1. A record review of personnel documents revealed 4 out of 14 testing personnel listed on the CMS-209 Personnel Report form, failed to have competency assessments performed at least semiannually during the first year of patient testing. 2.

An interview on September 19, 2018 at 10:25 AM, with the laboratory lead, confirmed the technical consultant failed to evaluate competency at least semiannually on 4 testing personnel since 2017.