

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  02D2113013	<b>(X3) Date Survey Completed</b>  09/06/2023
<b>Name of Provider or Supplier</b>  Mat-Su Valley Iii, Llc	<b>Street Address, City, State</b>  5851 S Knik-Goose Bay Road, Wasilla, AK	
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>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's 2022 and 2023 American Proficiency Institute (API) proficiency testing (PT) records and an interview with the Technical Supervisor, it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for the White Blood Cell Differential in two (2) out of three (3) Hematology testing events resulting in unsuccessful PT performance. See D2130</p>
<b>D2130</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p>

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's 2022 and 2023 American Proficiency Institute (API) proficiency testing (PT) records, and an interview with the technical consultant it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for the White Blood Cell Differential in two (2) out of three (3) Hematology events. Findings include: 1. A review of the laboratory's 2022 and 2023 API PT records revealed White Blood Cell Differential scores of less than eighty percent for the following hematology events: a. 2022-3: score of 0% b. 2023-2: score of 0% 2. An interview conducted on 9/6/23 at approximately 1:00 PM with the Technical Consultant confirmed the laboratory was unsuccessful in the PT events listed above 3. The laboratory reports performing approximately 500 White Blood Cell differentials annually.

**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 technical supervisor, the laboratory did not have a written procedure for notifying the health care providers and documenting imminently life threatening results, or panic, or alert values.

Findings include: 1. A request was made to review the procedure for reporting imminently life threatening results, or panic, or alert values and documentation could not be provided. 2. An interview conducted on 9/6/23 at approximately 1:00 PM with the Technical Consultant confirmed the laboratory did not have a procedure for reporting imminently life threatening results, or panic, or alert values 3. The laboratory reports performing approximately 2550 tests annually.

**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 review of testing person records and an interview with the technical consultant, the laboratory failed to ensure that personnel performing non-waived testing are qualified using diplomas or transcripts for six of eleven testing personnel records reviewed. Findings include: 1. A request was made to review the educational records for testing personnel performing non-waived testing, and documentation could not be provided for six of eleven testing testing personnel. 2. An interview conducted on 9/6/23 at approximately 1:00 PM with the Technical Consultant confirmed the laboratory did not have these diplomas or transcripts. 3. The laboratory reports performing approximately 2550 tests annually.