

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2254939	<b>(X3) Date Survey Completed</b> 11/29/2023
<b>Name of Provider or Supplier</b> Prosperity Labs Llc	<b>Street Address, City, State</b> 13890 Braddock Rd Suite 201, Centreville, VA	
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>D0000</b>	An announced initial CLIA survey was conducted at Mid Atlantic OBGYN on November 28-29, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies cited are as follows:
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: A. Based on a review of the laboratory's policies and procedures, quality control (QC) documentation, patient logs, Individualized Quality Control Plan (IQCP) and interviews, the laboratory failed to follow their established protocol for the performance of weekly UTI+ (Urinary Tract Infection) controls prior to reporting patient results for three (3) of nineteen (19) weeks reviewed from July 18, 2023 until November 28, 2023. The findings include: 1. Review of the laboratory's procedure manual revealed a procedure/protocol, "UTI+", for the determination of Urinary Tract Infection Pathogens using Real-Time Reverse transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) which stated, "4.2 Test Procedure An Analytical run begins with a weekly calibration plate (Figure 1) containing: 1.) One set of positive controls (each containing Taq polymerase, reverse transcriptase, Primers and probe for each pathogen and the endogenous control containing known amounts of DNA or RNA templates); 2.) One set of no template controls (containing Taq polymerase, reverse transcriptase, Primers and probe for each pathogen and the endogenous control, no template DNA or RNA is included). The QC plates confirm that all assays are generating C1 numbers within the confidence level generated during validations</p>

for each pathogen." and "6.6 Acceptable limits for Controls The positive control and endogenous control must show amplification to pass. The negative control must be negative to pass If all controls pass, then the patient results can be reviewed and released." 2. Review of the laboratory's records revealed an IQCP document with laboratory director approval on 07/13/2023, which stated "2.0 Quality Control Plan-Molecular Testing Assays Functional Testing documentation-FREQUENCY-Weekly and upon receipt of a new lot of reagents. ACCEPTANCE CRITERIA-Molecular testing assays will be verified of their functionality once per week using the manufacturers supplied controls when a new lot of assays are received." 3. Review of the laboratory's QC documentation for the UTI+ method from July 18, 2023 until the date of the survey on November 28, 2023 revealed a lack of documentation of QC performed for the RT-QPCR UTI method for the following weeks: 09/18/2023 (QC ran 09/11/2023 and on 09/26/2023), 10/11/2023 (QC ran on 10/04/2023 and 10/31/2023), 10/18/2023 (QC ran on 10/04/2023 and 10/31/2023), A total of 3 weeks. The surveyor requested to review documentation of the QC for the weeks listed above. The laboratory provided no documentation for review. 4. Review of the laboratory's Excel spreadsheet of patient's tested with the RT-QPCR UTI+ method revealed the following: 09/18/2023 to 09/25/2023-4 patients, 10/11/2023 to 10/18/2023-9 patients, 10/18/2023 to 10/31/2023-1 patient, A total of 14 patients. 5. In an exit interview with the general supervisor/testing personnel on November 29, 2023 at approximately 12:00 PM, the findings were confirmed. B. Based on a review of the laboratory's policies and procedures, quality control (QC) documentation, patient logs, Individualized Quality Control Plan (IQCP) and interviews, the laboratory failed to follow their established protocol for the performance of weekly vaginitis panel controls prior to reporting patient results for three (3) weeks of twenty (20) weeks reviewed from July 12, 2023 until November 28, 2023. The findings include: 1. Review of the laboratory's procedure manual revealed a procedures/protocols, "Vaginitis Panel", for the determination of Vaginal Pathogens using Real-Time Reverse transcriptase Quantitative Polymerase Chain Reaction (RT-QPCR) which stated, "4.2 Test Procedure An Analytical run begins with a weekly calibration plate (Figure 1) containing: 1.) One set of positive controls (each containing Taq polymerase, reverse transcriptase, Primers and probe for each pathogen and the endogenous control containing known amounts of DNA or RNA templates); 2.) One set of no template controls (containing Taq polymerase, reverse transcriptase, Primers and probe for each pathogen and the endogenous control, no template DNA or RNA is included). The QC plates confirm that all assays are generating C1 numbers within the confidence level generated during validations for each pathogen." and "6.6 Acceptable limits for Controls The positive control and endogenous control must show amplification to pass. The negative control must be negative to pass If all controls pass, then the patient results can be reviewed and released." 2. Review of the laboratory's records revealed an IQCP with laboratory director approval on 07/11/2023, which stated "2.0 Quality Control Plan-Molecular Testing Assays Functional Testing documentation-FREQUENCY-Weekly and upon receipt of a new lot of reagents. ACCEPTANCE CRITERIA-Molecular testing assays will be verified of their functionality once per week using the manufacturers supplied controls when a new lot of assays are received." 3. Review of the laboratory's QC documentation from July 12, 2023 until the date of the survey on November 28, 2023 revealed a lack of documentation of QC performed for the RT-QPCR Vaginitis method for the following weeks: 09/04/2023 (QC ran on 08/28/2023 and 09/13/2023), 10/11/2023 (QC ran on 10/04/2023 and 10/27/2023), 10/18/2023 (QC ran on 10/04/2023 and 10/27/2023). The surveyor requested to review documentation of the QC for the weeks listed above. The laboratory provided no documentation for review. 4. Review of the laboratory's Excel spreadsheet of patient's tested with the RT-QPCR UTI+ and

Vaginitis methods revealed the following: 09/04/2020 to 09/11/2023-3 patients, 10/11/2023 to 10/18/2023-8 patients, 10/18/2023 to 10/27/2023-3 patients, A total of 14 patients. 5. In an exit interview with the general supervisor/testing personnel on November 29, 2023 at approximately 12:00 PM, the findings were confirmed.

**D5411**

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

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on a laboratory tour, review of the laboratory's temperature and humidity records, instrument environmental/operating requirements, lack of documentation, and interview, the laboratory failed to monitor and document the relative humidity for ninety-two (92) of 92 days reviewed from July 3, 2023 to November 29, 2023. The findings include: 1. During a tour of the laboratory on November 28, 2023, at approximately 9:00 AM, the surveyor noted a BioRad CFX96 Real-Time PCR Detection System with a C1000 Touch Thermal Cycler in use for patient testing in the laboratory. 2. Review of the BioRad CFX96 Real-Time PCR Detection System Instruction Manual revealed the following instrument environmental/operating requirements, "Temperature-indoor use-Relative humidity maximum of 80% noncondensing." Review of the C1000 Touch Thermal Cycler Instruction Manual revealed the following: Environment requirements-Humidity Range 0-80%, non-condensing. 3. Review of the laboratory's temperature records from July 1, 2023 until November 29, 2023 revealed a lack of documentation of the relative humidity recordings for the following days from July 1, 2023 until November 29, 2023: 07/03/2023, 07/05/2023-07/07/2023, 07/10/2023-07/14/2023, 7/17/2023-7/21/2023, 07/24/2023-07/28/2023, 07/31/2023-08/4/2023, 08/07/2023-08/11/2023, 08/14/2023-08/18/2023, 08/21/2023-08/25/2023, 08/28/2023-09/01/2023, 09/05/2023-09/08/2023, 09/11/2023, 09/13/2023-09/15/2023, 09/18/2023-09/22/2023, 09/25/2023-09/29/2023, 10/02/2023-10/04/2023, 10/10/2023-10/13/2023, 10/17/2023, 10/23/2023-10/24/2023, 10/27/2023, 10/30/2023-11/3/2023, 11/06/2023-11/08/2023, 11/10/2023, 11/14/2023-11/17/2023, 11/20/2023-11/22/2023, 11/27/2023-11/29/2023. Total of 92 days of 92 days reviewed. The surveyor requested to review documentation of the relative humidity for the above listed 92 days. The laboratory provided no documentation to review. 4. In an exit interview with the general supervisor/testing personnel on November 29, 2023 at approximately 12:00 PM, the findings were confirmed.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies and procedures, monthly quality control

(QC) records, temperature logs and an interview, the laboratory failed to follow their "Laboratory Quality Assurance Plan" to monitor/review QC and temperature logs monthly in order to monitor, assess and correct problems within the speciality of Microbiology for two (2) of four (4) months of QC and temperature logs reviewed from July 2023 until October 2023. The findings include: 1. Review of the laboratory's policies and procedures revealed a quality assurance (QA) plan to monitor, assess and correct problems within the speciality of Microbiology that outlined the laboratory director (LD) was to review Quality Control logs and Temperature logs on a monthly basis. 2. Review of the laboratory's monthly QC logs for the UTI+ (urinary tract infection) and Vaginitis methods and temperature logs from July 2023 to October 2023 (4 months) revealed the laboratory director did not sign as reviewed the QC or temperatures logs for September 2023 and October 2023, a total of 2 months. The surveyor requested to review documentation of the QC document review for September 2023 and October 2023. The laboratory provided no documentation for review. In an interview with the General supervisor (GS) on November 28, 2023, at approximately 1:15 PM, the GS stated they had emailed the documents to the laboratory director but had not received the reviewed/signed documents back yet. 3. In an exit interview with the general supervisor/testing personnel on November 29, 2023 at approximately 12:00 PM, the findings were confirmed.