

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2278293	(X3) Date Survey Completed 03/18/2024
Name of Provider or Supplier Prism Molecular	Street Address, City, State 1801 Main Street, Suite 104, Blakely, PA	
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
D6086	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory director (LD), the LD failed to ensure that verification procedures were established and performed to ensure the laboratory information system (LIS) implemented performed acceptably before reporting patient test results from 12/07/2023 to the date of the survey. Findings Include: 1. On the day of survey, 03/18/2024 at 12:15 pm, the laboratory failed to provide a policy and documentation of the verification procedures performed to determine if the LIS performs acceptably before reporting patient test results when the laboratory's EDEN LIS was implemented from 12/07/2023 to 03/18/2024. 2. The LD confirmed the findings above on 03/18/2024 at 01:00 pm.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, lack of documentation, and interview with testing personnel #1 (TP), the laboratory director (LD) failed to ensure that QC programs were established and maintained to ensure the quality of services</p>

provided and to identify failures in quality as they occur for microbiology testing performed on the Thermo Fisher Quant Studio 12K Flex analyzer from 02/02/2024 to the date of the survey. Findings Include: 1. The laboratory's Quality Management and Assessment Plan states, "4.2.6 Quality Standards-Standards and Controls, 4.2.6.7 If control values fall outside of defined parameters, the run is repeated." 2. On the day of the survey, 03/18/2024, the laboratory could not provide documentation for the repeated runs performed when the following control values fell outside of the the laboratory's defined parameters when microbiology testing was performed on 1 of 1 Thermo Fisher Quant Studio 12K Flex analyzer from 02/02/2024 to 03/18/2024: - 02/02/2024: RPP Viral 2: Positive Control for Paraflu4, RV1, and RV2 - 02/20/2024: RPP Bacterial 1: L. pneumo - 02/21/2024: RPP Viral 4: EV pan, Paraflu1, Paraflu4 3. TP # 1 confirmed the findings above on 03/18/2024 at 01:00 pm.

D6094

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

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.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the laboratory director (LD), the laboratory director (LD) failed to ensure a QA program was established and maintained to ensure the quality of services provided by the laboratory from 12/07/2023 to the date of the survey. Findings include: 1. On the date of the survey, 03/18/2024 at 12:45 pm, the laboratory could not provide a procedure for the periodic QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes from 12/07/2023 to 03/18/2024. 2. The LD confirmed the finding above on 03/18/2024 at 01:00 pm.