Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2087560	06/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Principle Labs, Llc	2550 Brodhead Road, Suite 105, Bethlehem, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a lack of documentation and interview with the Quality Assurance (QA) supervisor, the laboratory failed to follow an established competency assessment procedure to assess the competency of 1 of 2 Technical Supervisor (TS) and 1 of 1 General Supervisor (GS) for their supervisory responsibilities performed from 2021 through 2023. Findings include: 1. The laboratory's Competency policy states, "Each employee has competency assessed and documented for each procedure the employee performs. For new employees, after initial training, competency will be done at 6 months, then 6 months later (1 year anniversary) and annually thereafter. Competency of consultants and supervisors is assessed against the CLIA defined responsibilities of the position(s) that they hold." 2. On the day of the survey, 06/17/2024 at 09:46 am, the laboratory could not provide competency assessment documents to assess the competency of the following individuals for their supervisory responsibilities performed from 2021 to 2023: - TS #1 (CMS 209 personnel #2) for 2022 and 2023 - GS #1 (CMS 209 personnel #3) for 2021, 2022 and 2023 3. The QA supervisor confirmed the findings above on 06/17/2024 at 1:55 pm.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with the Quality Assurance (QA) supervisor, the laboratory failed to verify the accuracy of PT results obtained for 3 of 3 API Microbiology testing events in 2023. Findings Include: 1. The API Proficiency Testing performance Evaluation form states "Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. On the day of survey, 06/17/2024 at 10:25 am., review of the laboratory's API Microbiology PT records revealed that the laboratory did not verify the accuracy for the following analytes that were not graded by the PT agency in 2023: Molecular Mycology (urine) 1st, 2nd & 3rd events - Candida sp. Molecular Resistance Genes (urine) 1st event - CTX-M Group 1 & 2, dfrA, ErmA, ErmB & ErmC, IMP, KPC, mecA, OXA-23, OXA-48, qnrA. qnrB, SHV, TEM, vanA, vanB, VIM Molecular Resistance Genes (urine) 2nd event - CTX-M Group 1 & 2, dfrA, Erm, IMP, KPC, mecA, OXA-23, OXA-48, qnr, SHV, Sul, TEM, vanA, vanB, VIM Molecular Resistance Genes (urine) 3rd event - CTX-M, dfrA, Erm, IMP, KPC, mecA, OXA, OXA-48, qnr, SHV, Sul, TEM, vanA, vanB, VIM 3. The QA supervisor confirmed the findings above on 06/17/2024 at 1:55 pm.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with the Quality Assurance (QA) supervisor, the laboratory failed to verify the accuracy of the PT results obtained for 1 of 3 API Microbiology testing events in 2023. Findings include: 1. The API Proficiency Testing performance Evaluation form states " Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. On the day of survey, 06/17/2024 at 10:25 am., review of the laboratory's API PT records revealed that the laboratory did not verify the accuracy for the following analytes that were not scored by the PT agency in 2023: UTI Panel (Molecular Bacti-Urine) 3rd event - Aerococcus urinae (UTI-15). - Ureaplasma urealyticum (UTI-14). 3. The QA supervisor confirmed the findings above on 06/17/2024 at 1:55 pm.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records, and interview with the Quality Assurance (QA) supervisor, the Laboratory Director did not ensure that all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that required corrective action in Virology in 2022 and 2023. Findings include: 1. The laboratory's policy "L-20-C- Job Description for Lab Testing Personnel " effective 06/12/2015 and signed by the Laboratory Director, lists job expectations for the Laboratory Medical Director to include "All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action." 2. On the day of survey, 06/17/2024 at 10:25 am, review of 27 CAP PT records revealed the Laboratory Director's review of the PT reports was not documented and no signature was found for review of the following evaluation reports: 2022 - SARS-CoV-2 2nd event - Pharmacogenetics 2nd event - Infectious Disease, Respiratory 3rd event 2023 - Pharmacogenetics 1st & 2nd event - Infectious Disease, Respiratory 1st & 3rd event 3. The QA supervisor confirmed the findings above on 06/17/2024 at 1:55 pm.