Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0683066	02/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pima County Health Department	1493 W Commerce Court, Tucson, AZ	

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 review of employee competency policies and procedures and interview with the technical consultant, (A) the laboratory failed to establish policies and procedures to assess the competency of the Technical Consultant and (B) the laboratory failed to follow established policies to assess the competency of testing personnel. Findings include: A1. The CMS-209, Laboratory Personnel form submitted for review during the survey conducted on February 8, 2023 listed one Technical Consultant who provides technical oversight for testing performed in the specialty of Microbiology. A2. No documentation was presented for review to indicate the laboratory established policies and procedures to assess the competency of the Technical Consultant. A3. The technical consultant interviewed on 2/08/23 at 2:10pm confirmed that the laboratory did not have policies and procedures established to assess the competency of the technical consultant. B1. The laboratory's established policy titled, "Quality Assurance Program (QA)" states, "Personnel performing laboratory tests must undergo an initial training and annual or bi-annual review of assigned tasks by the Technical Consultant." B2. The laboratory failed to follow their established policy indicated above to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. See D6053 for specific findings. B3. The technical consultant interviewed on 2/08/23 at 4:35pm confirmed that the laboratory failed to follow the established policy referenced above to assess the competency of testing

	personnel bi-annually during the first year the individuals tested patient specimens. B4. The laboratory performs Gram Stain and Wet Mount testing in the specialty of Microbiology with a reported annual test volume of 1,200.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: (A) Based on review of Proficiency Testing (PT) records from 2021 and 2022, review of established Quality Assessment (QA) policies and procedures and interview with the technical consultant, the laboratory failed to follow established QA policies to document corrective action for unsatisfactory PT scores for the regulated analyte, Gram Stain; and (B) based on review of the laboratory's established QA policies and procedures, and interview with the facility personnel, the laboratory's QA procedures failed to identify and correct problems found with employee competency. Findings include: A1. The laboratory's established QA policy titled, "Quality Assurance Program" states, "The Technical Consultant will monitor (PT) results, investigate all unacceptable responses, and recommend corrective actions." A2. No documentation of corrective action was presented for review during the survey to indicate the laboratory followed their established policy referenced above to investigate and correct issues found with unacceptable PT scores received for Gram Stain testing from the 2nd event of 2021 and the 2nd event of 2022. See D5293 for specific findings. A3. The technical consultant interviewed on 2/08/23 at 4:45pm confirmed that the laboratory failed to follow their established QA policy and procedure to document corrective action for the unsatisfactory PT scores referenced above. B1. The laboratory's established QA policy titled, "Quality Assurance Program (QA)" states, "The QA is to be evaluated each month by the Technical Consultant and a report provided to the Laboratory Director. A review will be submitted to each Program, the Laboratory Director, and the Clinical Consultant at least quarterly." B2. The laboratory's QA processes failed to identify and correct issues found with missing competency evaluations for laboratory personnel. See D5209 and D6053 for specific findings. B3. The technical consultant interviewed on 2/08/23 at 4:45pm confirmed that the laboratory's QA processes indicated above failed to identify and correct errors found with missing competency evaluations for laboratory personnel.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment (QA) records and interview

	with the technical consultant, it was determined that the laboratory failed to document corrective actions taken to resolve problems associated with unsatisfactory Proficiency Testing (PT) scores. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Bacteriology, with an approximate annual test volume of 350. 2. The laboratory participates in PT under the sub-specialty of Bacteriology for the regulated analyte, Gram Stain, and received an unsatisfactory score of 60% for the second testing event of 2021 and second testing event of 2022. 3. No corrective action documentation was presented for review during the survey to indicate the laboratory investigated and resolved problems associated with the unsatisfactory PT scores indicated above. 4. During the survey conducted on February 8, 2023 at approximately 2:40pm, the technical consultant confirmed the laboratory failed to document corrective action for the unsatisfactory PT scores indicated above.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) records, established QC policies and procedures and interview with the technical consultant, the laboratory failed to document positive and negative reactivity using control organisms each week of use for gram stains. Findings include: 1. The laboratory performs Gram Stain testing in the sub-specialty of Bacteriology with an approximate annual test volume of 350. 2. The laboratory's established policy titled, "Urethral Smears For Gram Stains" states, "A slide, with known Gram positive and Gram negative organisms on it, is stained with the first patient smear of the clinic, at least once per week, and with each new lot of any reagent." 3. Review of the laboratory's Gram Stain QC Log from January 2021 through January 2023 indicated the laboratory failed to perform and document positive and negative reactivity using control organisms each week of use for gram stains as evidenced by: - Gram Stain QC was performed on 4/26/22 and not again until 5/11/22. Two patients (#22688 and 90100) were tested on 5/03/22, during that timeframe. - Gram Stain QC was performed on 6/29/22 and not again until 7/25/22. Four patients were tested during that timeframe. Patient #126427 was tested on 7/08 /22; Patient's #104467 and #20732 were tested on 7/12/22; and Patient #47514 was tested on 7/14/22. - Gram Stain QC was performed on 11/04/22 and not again until 12 /11/22. Two patients were tested during that timeframe. Patient (#50937) was tested on 11/17/22 and patient (#138232) was tested on 11/21/22. 4. The technical consultant interviewed on 2/08/23 at approximately 4:00pm confirmed that the laboratory failed to perform and document positive and negative reactivity using control organisms each week of use for gram stains, as indicated above.
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 review of Quality Assessment (QA) documentation, analytic test records, laboratory policies and procedures and interview with the technical consultant, the laboratory's established QA policies and procedures failed to monitor, assess and, when indicated, correct problems identified in the analytic systems. Findings include: 1. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with a lack of Quality Control (QC) records for Gram Stain testing performed in the sub-specialty of Bacteriology. See D5503 for findings. 2. The technical consultant interviewed on 2/08/23 at 4:45pm confirmed that the laboratory's QA processes were not effective at monitoring, identifying and correcting problems found in the analytic systems.
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 lack of performance evaluation documentation and interview with the technical consultant, the technical consultant failed to evaluate and document the performance of two testing personnel, at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. During the survey conducted on 2/08/2023, no semiannual competency evaluation documentation was presented for review for two out of two testing personnel who perform patient testing in the specialty of Microbiology. Testing Personnel (TP-1) began patient testing in January 2022 and TP-2 began patient testing in May 2022. 2. The technical consultant interviewed on 2/08/23 at 2:20pm confirmed that the laboratory failed to document a semiannual competency evaluation for the two testing personnel indicated above. 3. The laboratory performs Gram Stain and Wet Mount testing in the specialty of Microbiology with a reported annual test volume of 1,200.