Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0188598	06/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Keystone Urology Specialists	2106 Harrisburg Pike Suite 200, Lancaster, 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 review of competency assessment records and interview with testing personnel (TP) #5 (CMS 209), the laboratory failed to establish a competency assessment procedure to assess 2 of 2 technical supervisors (TS) for their supervisory responsibilities for Histopathology testing from 05/05/2021 to the day of survey. Findings Include: 1. On the day of survey, 06/22/2023 at 11:38 AM, the laboratory could not provide a competency assessment procedure to assess the competency for 2 of 2 TS (CMS 209 personnel #1, and #2) for their supervisory responsibilities for Histopathology testing from 07/14/2021 to the day of survey. 2. The laboratory could not provide competency assessment documentation for the 2 of 2 TS. 3. TP #5 confirmed the findings above on 06/22/2023 around 12:30 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 the review of the American Proficiency Institute (API) records and interview with testing personnel (TP) #3 (CMS 209), the laboratory failed to verify the accuracy of analytes assigned a proficiency testing (PT) score that does not reflect laboratory test performance for 1 of 1 chemistry PT event in 2023. Findings include: 1. On the day of the survey, 06/21/2023 at 12:15 PM, a review of API PT records revealed the laboratory received 0% on the following tests - API 1st Event Chemistry Core 2023- Albumin - API 1st Event Chemistry Core 2023- Alkaline Phosphate - API 1st Event Chemistry Core 2023 -Aspartate aminotransferase - API 1st Event Chemistry Core 2023- Total Bilirubin - API 1st Event Chemistry Core 2023- Total Calcium - API 1st Event Chemistry Core 2023- Chloride - API 1st Event Chemistry Core 2023- Creatinine - API 1st Event Chemistry Core 2023- Glucose - API 1st Event Chemistry Core 2023- Potassium - API 1st Event Chemistry Core 2023- Sodium - API 1st Event Chemistry Core 2023- Total Protein - API 1st Event Chemistry Core 2023- Blood Urea Nitrogen 2. The laboratory failed to provide the verification of accuracy for the analytes listed above that scored a 0% for API 1st Event Chemistry Core 2023. 3. TP #3 confirmed the above findings on 06/21/2023 at 14:30 PM.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with testing personnel (TP) #3 (CMS 209), the laboratory failed to document all proficiency testing evaluation and verification activities for 2 of 3 Microbiology and 3 of 3 Chemistry Core events in 2022. Findings Include: 1. On the day of survey, 06/21/2023 at 11:51 AM, a review of the API PT records revealed that the laboratory failed to document evaluations and verifications for the following events in 2023. - Microbiology-Bacteriology Molecular Bacti-Urine- 2022 1st Event- 97% - Microbiology- Bacteriology Molecular Bacti-Urine- 2022 2nd Event- 94% - Chemistry Core- Routine Chemistry- Albumin- 2022 1st Event- 80% - Chemistry Core- Routine Chemistry-Chloride- 2022 2nd Event- 80% - Chemistry Core- Routine Chemistry- Chloride- 2022 3rd Event- 80% 2. API 2022 1st Event Chemistry Core attestation form signed by the Laboratory Director said 100% grade was achieved for the event. 3. TP # 3 confirmed the above findings on 06/21/2023 at 14:50 PM.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of the temperature records, and an interview with the Testing Personnel (TP) #3 (CMS 209), the laboratory failed to define criteria for Humidity,

	and Fridge Temperature for Histopathology testing from 05/05/2021 to the day of survey. Findings include: 1. On the day of the survey, 06/22/2023, a review of the laboratory's temperature logs revealed that the laboratory did not have acceptable Humidity, and Fridge Temperature ranges for 17 of 17 months of logs. 2. According to TP #3, Immunohistochemical stains were stored in the fridge and an observation of the laboratory revealed that Histopathology blocks were stored in the laboratory. 3. Interview with TP #5 confirmed the findings above on 06/22/2023 at 12:31 PM.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on an observation of the laboratory and an interview with testing personnel (TP) #3 (CMS 209), the laboratory failed to perform and document maintenance as defined by the manufacturer and the frequency specified by the manufacturer for the thermometer used to record temperature for ABX Micros 60/ABX Micros ES 60 hematology, Access 2 Chemistry and Clinitek Advantus urinalysis reagent storage from 2021 to 06/21/2023. Findings Include: 1. On 06/21/2023 at 14:25 PM, an observation of the laboratory revealed that the following thermometers were used for recording Room Temperature (RT) and expired. -Traceable, S/N 192747163 Expired on 12/30/2021. 2. The following reagents were stored in the laboratory at RT. - NERL Reagent Grade Water for ABX Micros 60/ABX Micros ES 60 - 1 Pack. - Siemens Multistix 10 SG for - 2 Pack. - ABX Minidil LMG ABX Micros 60/ABX Micros ES 60- 1 Pack. - Access Wash Buffer II- 1 Pack. - Citranox- 1 Pack. - Contrad 70- 2 Pack. 3. Interview with TP #3 confirmed the findings above on 06/22/2023 at 11:30 AM.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a lack of documentation, observation of the laboratory, and an interview with testing personnel (TP) #3 (CMS), the laboratory failed to establish a maintenance protocol that ensures equipment performance for 2 of 2 pipettes and 2 of 2 thermometers used for Complete Metabolic Panel and Complete Blood Count testing from 05/05/2021 to 06/21/2023. Findings include: 1. At the time of the survey, on 06 /21/2023 at 14:10 PM, an observation of the laboratory revealed that the laboratory failed to document calibration activities for the following instruments. - MLA Pipette- Vistalab - MLA Pipette- Dimond PRO. - Therm PRO- Thermometer. - Traceble

	Thermometer. 2. The laboratory failed to provide a calibration protocol for the accuracy of the pipettes and thermometer listed above. 3. TP ## confirmed the findings above on 06/22/2023 at 11:45 PM.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the Laboratory's Procedures Manual, competency records, and interview with technical supervisor (TS) #1 (CMS 209), and testing personnel (TP) #5 (CMS 209), the TS failed to evaluate the competency of 2 of 4 TP (TP#1 and TP#2, CMS 209) who performed histopathology slide review from 05/05/2021 through the date of the survey. Findings Include: 1. The Keystone Urology Employee Profile, Personnel Training, CE, Competency procedure section 4 states that All TP are subject to competencies per CLIA regulations. 2. On the day of survey, 06/22/2023, TS # 1 could not provide documentation of competency assessments performed for 2 of 4 TP who performed Histopathology Slide reviews from 2021 through the date of survey. 3. TS #1 and TP #5 confirmed the findings above on 06/22/2023 at 12:15 PM.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on a review of the laboratory's competency assessment (CA) records and interview with technical supervisor (TS) #1 (CMS 209), TS #1 failed to assess test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for 1 of 4 testing personnel (TP) who performed Grossing for Histopathology Testing from 05/05/2021 to 06/22/2023. Findings include: 1. On the day of inspection, 06/22/2023 at 11:30 AM, a review of TP competency assessment records revealed that the TS did not perform a competency assessment through previously analyzed specimens, external proficiency testing samples, or internal blind testing samples for 1 of 4 TP (CMS 209 TP#5) that performed grossing for histopathology testing from 2021 through the day of the survey. 2. The laboratory performed 8862 Histopathology Tests in 2022 (CMS 116). 3. Technical Supervisor (TS) #1 confirmed the above findings on 06/22/2023 at 11:48 AM.