Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0188598	04/24/2025
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation and interview with the laboratory manager (LM), the Laboratory Director (LD)/designee and testing personnel (TP) failed to attest to the routine integration of samples into the patient workload for 2 of 4 API PT events performed in 2023 and 2 of 6 API PT events performed in 2024 for Chemistry and Hematology. Findings include: 1. On the day of survey 04/24/2025, review of the laboratory's API PT records revealed, the LD/designee and TP failed to document the attestation of the routine integration of samples into the patient workload for the following 2 of 4 API PT events performed in 2023 and 2 of 6 API PT events performed in 2024: - API 2023 Chemistry Core 2nd and 3rd Events - API 2024 Chemistry Core 3rd Event - API 2024 Hematology/Coagulation 2nd Event 2. The LM confirmed the findings above on 04/24/2025 at 12:06 pm.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of the laboratory's temperature logs, lack of documentation and interview with the laboratory manager (LM), the laboratory failed to document and define acceptable criteria for room temperature and humidity to ensure proper test system operating conditions and proper reagent storage were met for 1 of 1 Siemens Clinitek Advantus analyzer used to perform urinalysis examinations from 06/21/2023 to 04/24/2025. Findings include: 1. On the day of survey, 04/24/2025, review of the laboratory's temperature logs revealed the laboratory failed to document and define acceptable criteria for room temperature (manufacturer's acceptable range 18 to 30 degrees Celsius) and humidity (manufacturer's acceptable range 20 to 80 %) for 1 of 1 Siemens Clinitek Advantus analyzer (s/n KPS63092309) used to perform urinalysis examinations from 06/21/2023 to 04/24/2025. 2. The hours of laboratory testing are Monday-Friday 08:00 am to 05:00 pm (CMS 116). The laboratory could not provide documentation of temperature and humidity taken for 192 of 673 days when the laboratory was closed. 3. The laboratory performed 21,000 urinalysis examinations in 2024 (CMS 116). 4. The LM confirmed the above findings on 04/24/2025 at 12:06 pm. * REPEAT DEFICIENCY
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 review of quality assurance (QA) records, lack of documentation and interview with the laboratory manager (LM), the Laboratory Director (LD) failed to ensure a QA program was maintained and documented to ensure the quality of services provided by the laboratory for 5 of 5 months from April 2024 to August 2024. Findings include: 1. The laboratory's Quality Assurance Program policy states, "A quality assurance checklist is completed by the Laboratory Supervisor monthly." 2. On the day of survey, 04/24/2025, the laboratory failed to provide documentation of the monthly QA checklist used to assess the laboratory's pre-analytical, analytical, and post-analytical processes for 5 of 5 months from April 2024 to August 2024. 3. The LM confirmed the findings above on 04/24/2025 at 12:06 pm.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)

	(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory manager (LM), the laboratory failed to have the required records accessible for 1 of 3 testing specialties (histopathology) to review during the laboratory survey performed on 04/24/2025. Findings Include: 1. On the day of the survey, 04/24/2025 at 11:30 am, the laboratory could not provide the following records upon request: - Proficiency testing/peer review records for histopathology microscopic examinations performed from 06/21 /2023 to 12/01/2024. - Quality control records for stains used for histopathology microscopic examinations performed from 06/21/2023 to 12/01/2024. - Procedure manual used for histopathology microscopic slide preparations and examinations performed from 06/21/2023 to 12/01/2024. 2. The LM confirmed the findings above on 04/24/2025 at 12:06 pm.