Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0188598	05/05/2021
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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records and interview with the Testing Personnel (TP) #2, the laboratory failed to provide 1 of 3 API PT attestation statements for chemistry PT performed in 2020. Findings include: 1. On the day of survey, 05/05/2021, the TP#2 could not provide the 2020 chemistry 1st Event attestation statement. 2. The TP#2 confirmed the finding above on 05/05/2021 at 09:20 am.
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: A. Based on review of the laboratory's Employee Competency procedure and interview with Testing Personnel (TP) #2, the laboratory failed to have a complete policy to assess the competency of 2 of 2 laboratory personnel who performed the Clinical consultant (CC), Technical Supervisor (TS), and General Supervisor (GS) roles from 10/01/2018 to the date of survey. Findings include: 1. On the day of survey, 05/05/2020, the TP#2 could not provide a competency assessment policy to assess the competency of the following personnel from 10/01/2018 to the date of survey: - 2 of 2 CC (on CMS 209, listed as personnel #2 and #8) - 1 of 1 TS (on CMS

	209, listed as personnel #2) - 1 of 1 GS (on CMS 209, listed as personnel #8) 2. The TP#2 confirmed the finding above on 05/05/2021 around 12:20 p.m. B. Based on review of the laboratory's Employee Competency procedure, annual competency records, and interview with Testing Personnel (TP) #2, the laboratory failed to establish a complete procedure that includes all six components required for competency assessment for all TP who performed Post Vasectomy Vas Drop examinations from 10/01/2018 to the date of survey. Findings include: 1. On the day of survey, 05/05/2021, the Post Vasectomy Competency policy reviewed at the time of survey did not include the following: - Direct observations of performance of instrument maintenance and function checks - Assessment of test performance through testing previously analyzed specimens, internal blind samples or external proficiency testing samples - Assessment of problem-solving skills 2. The following number of specimens were examined for Post Vasectomy Vas Drop: - 10/01/2018 to 12/31/2018: 198 specimens - 2019: 700 specimens - 2020: 576 specimens 3. The TP #2 confirmed the findings above on 05/05/2020 around 12:20 p.m.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the testing Personnel (TP)#2, the laboratory failed to verify twice annually the accuracy of Post Vasectomy examination tests performed from 10/01/ 2018 through the date of survey. Findings include: 1. On the day of survey, 05/05/2021, the laboratory could not provide documentation of verification of accuracy for Post Vasectomy examination tests performed from 10/01/2018 through the date of the survey. 2. The following Post Vasectomy Vas Drop examinations were performed: - 10/01/2018 to 12/31/2018: 198 specimens - 2019: 700 specimens - 2020: 576 specimens 3. The TP#2 confirmed the findings above on 05/05/2021 at 9:30 a.m.
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 observation of the laboratory and interview with the testing personnel (TP) #2, the laboratory failed to establish a maintenance policy to assess the maintenance /function for 2 of 2 Tempcheck red spirit thermometers used to monitor the temperature for refrigerators in the main laboratory and Cytology laboratory and 1 of 1 Thermo Fisher Scientific digital thermometer for room temperature in Cytology from 10/01/2018 to the day of survey. Findings Include: 1. On the day of survey, 05/05

	/2021, the laboratory could not provide a maintenance policy for the thermometers. 2. The laboratory could not provide maintenance records for the following thermometers used to store quality control materials: - 2 of 2 Tempcheck red spirit thermometers used to monitor the temperature of refrigerators: Main Laboratory Frigidaire Refrigerator (Cat#240043 Lot #81720550) Cytology Refrigerator (Cat#240043 Lot# 23000550) - 1 of 1 Thermo Fisher Scientific digital thermometer for cytology room temperature used to store reagents. 3. An expiration date of 04/13/2011 was observed on the sticker posted on the Thermo Fisher Scientific digital thermometer. 4. TP #2 confirmed the findings above on 05/05/2021 at 12:00 p.m.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of urine sediment microscopic examination quality control (QC) records and interview with Testing Personnel (TP) #2, the laboratory failed to include a positive control material each day of patient testing for urine sediment microscopic examination for casts and crystals from 10/01/2018 to the date of survey. Findings Include: 1. On the day of survey, 05/05/2021, review of urine sediment microscopic examination QC records revealed the laboratory did not include a positive control each day of patient testing for casts and crystals from 10/01/2018 to the date of survey. 2. The following urine sediment microscopic examinations were performed: - 10/01/2018 to 12/31/2018: 4931 specimens - 2019: 18,200 specimens - 2020: 13.421 specimens 3. The TP#2 confirmed the findings above 05/05/2021 at 11:15 a.m.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records and interview with Testing Personnel (TP)#2, the Laboratory Director's (LD) failed to identify problems that required corrective action for 1 of 3 Hematology /coagulation events in 2019, 1 of 3 Chemistry-Core events in 2020, and 1 of 1 Chemistry-Core events in 2021 . Findings include: 1. On the day of survey, 05/05 /2021, the review of PT records revealed the following: - 2019 API Hematology /coagulation 3rd event did not state an acceptable plan of correction for Urine Sediment. The laboratory received a 50% score. - 2020 API Chemistry-Core 1st event did not have a plan of correction for Chloride. The laboratory received a 40% score. -

	2021 API Chemistry-Core 1st event did not have a plan of correction for Sodium. The laboratory received an 80% score. 2. 13.421 urine sediment microscopic examinations were performed in 2019 - 288 Chloride tests performed from 10/1/2019 to 06/30/2020 - 209 Sodium tests performed in 2021 3. The TP#2 confirmed the findings above on 05 /05/2021 at 09:25 a.m.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(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 review of competency assessment records, American Proficiency Institute (API) proficiency testing (PT) records, and interview with testing personnel (TP)#2, the Technical Consultant failed to assess the competency of 1 of 7 TP (listed on CMS 209 Personnel #6) through internal blind testing samples or external PT samples in 2019 and 2020. Findings Include: 1. On the day of survey,05/05/2021, the competency assessment records revealed the laboratory did not assess the competency of TP#6 through internal blind testing samples or external PT samples in 2019 and 2020 a. TP#6 performed endocrinology test on the Access II in 2019 and all other tests performed in the laboratory in 2020 2. TP#2 confirmed the findings above on 05 /05/2021 around 12:25 p.m.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with testing personnel (TP)#2, the laboratory director failed to specify in writing the responsibilities and duties of each individual involved in patient testing and supervisory personnel at the time of survey. findings Include: 1. On the day of survey, 05/05/2021, the laboratory could not provide written job responsibilities and duties for the testing personnel, clinical consultant, technical supervisor, and general supervisor. 2. The TP#2 confirmed the finding above on 05/05/2021 around 12:25 p.m.