Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2092903	(X3) Date Survey Completed 11/30/2021
Name of Provider or Supplier Kansas City Skin & Cancer Center	**Street Address, City, State** 9301 W 74th Street, Suite 230, Shawnee Mission, KS	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of proficiency testing (PT) records, the laboratory fails to test proficiency testing samples in the same manner as patient's specimens. See D2006. This laboratory was previously cited for failure to test proficiency testing samples in the same manner as patient's specimens under D2015 on 8/23/2019.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

	This STANDARD is not met as evidenced by: Based on the review of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) documentation and interview with the general supervisor (GS) #2, the laboratory failed to examine or test, as applicable, the proficiency testing samples in the same manner as it tests patient specimens. This occurred for four of four PT testing events in 2020 and 2021. Findings: 1. Review of the laboratory's 2020 and 2021 WSLH PT documentation found Potassium Hydroxide (KOH) prep PT samples tested in multiples as follows: a. 2020 Micro QA1: Result pages showed testing was performed by two testing personnel for three of three samples: Slide 1, Slide 2, and Slide 3 on the same date of 4/16/2020. The attestation page has signatures for three testing personnel. Submission of PT results cuttoff date was 5/1/2020. b. 2020 Micro QA2: Result pages showed testing was performed by five testing personnel for three of three samples: Slide 4, Slide 5, and Slide 6 on 10/15 /2020 and 10/16/2020. All five testing personnel signed the attestation page. Submission of PT results cuttoff date was 10/30/2020. c. 2021 Micro QA1: Result pages showed testing was performed by four testing personnel for three of three samples: Slide 1, Slide 2, and Slide 3 on 4/15/2021 and 4/16/2021. All four testing personnel signed the attestation page. Submission of PT results cuttoff date was 4/30 /2021. d. 2021 Micro QA2: Result pages showed testing was performed by four testing personnel for three of three samples: Slide 4, Slide 5, and Slide 6 on 10/21 /2021 and 10/22/2021. The attestation page has signatures for two testing personnel. Submission of PT results cuttoff date was 10/29/2021. 2. GS #2 stated the laboratory does not have more than one testing personnel perform patient testing for KOH exams. Interview on 11/30/21 at 1:20 p.m. with GS #2 confirmed, the laboratory failed to examine or test, as applicable, the proficiency testing samples in the same manner as it tests patient specimens.