

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0938492	(X3) Date Survey Completed 02/05/2018
Name of Provider or Supplier Uc Health Dept Of Dermatology	Street Address, City, State 3590 Lucille Drive, Suite 1600, Cincinnati, OH	
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
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>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 preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and an interview with the Testing Personnel (TP), the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems. Findings Include: 1. Review of "Laboratory Standard Operating Procedure" manual found no mention of preanalytic quality assessment policy and procedures. 2. The Surveyor requested the laboratory's preanalytic quality assessment policy and procedures on the date of inspection. The TP confirmed on 02/05/2018 at 10:40 AM, the laboratory did not have a preanalytic quality assessment policy and procedure and was unable to provide the requested documentation on the date of inspection.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP), the laboratory</p>

failed to follow written policies and procedures and document all activities of the daily quality control for H&E reagents. Findings Include: 1. Review of the laboratory's "Laboratory Standard Operating Procedure LSOP-Mohs-020" policy and procedure provided on the date of the inspection, revealed the following statements: "Linear Stainer and manual staining requires multiple changes of solutions throughout the day in order for the slide staining to be optimal." "...The hematoxylin and eosin shall be replaced with fresh reagent on Mondays. The hematoxylin must be filtered each morning prior to staining." "...The Toluidine Blue and H&E stains are monitored on the daily QC/QA sheet." 2. The surveyor requested the daily QC/QA sheet for the reagent changes during 2016, 2017 and 2018 from the TP. 2. The TP confirmed the laboratory did not have daily QC/QA sheets and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/05/2018 at 10:30 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 direct observation, record review, and an interview with Testing Personnel (TP), the laboratory failed to establish and document a maintenance protocol that ensured microscope performance which was necessary for accurate and reliable test results and test result reporting. Findings Include: 1. Direct observation of the histopathology laboratory on the date of the inspection revealed an Olympus BX-40 microscope utilized for histopathology slide, tissue, and stain quality prior to sending the case for interpretation. 2. Review of the laboratory's policies and procedures did not find any mention of daily/as needed microscope maintenance procedures. 3. The Surveyor requested the laboratory's microscope maintenance policy and procedure and 2015, 2016, and 2017 daily/as needed microscope maintenance documentation from the TP. The TP stated the laboratory had not established a microscope maintenance policy and procedure, had not documented internal daily/as needed microscope maintenance activities in 2015, 2016, and 2017, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/05/2018 at 11:05 AM.

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 record review and an interview with Testing Personnel (TP), the laboratory failed to establish and follow written policies and procedures and document all assessment activities of the ongoing mechanism to monitor, assess, and correct problems identified in the analytic systems. Findings Include: 1. Review of the laboratory's "Laboratory Standard Operating Procedure" policy and procedure provided on the date of the inspection, found no mention of an ongoing review process for analytic laboratory functions. 2. The Surveyor requested the laboratory's 2016, 2017, and 2018 analytic systems quality assessment documentation from the TP. The TP confirmed the laboratory did not have any quality assessment policy and procedures established, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/05/2018 at 10:30 AM.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on record review and an interview with Testing Personnel (TP), the laboratory failed to establish and follow written policies and procedures and document all assessment activities of an ongoing mechanism to monitor, assess, and correct problems identified in the postanalytic systems. Findings Include: 1. Review of the laboratory's "Laboratory Standard Operating Procedure", manual provided on the date of the inspection, found no mention of an ongoing review process for postanalytic laboratory processes. A 2016 "QA Record Keeping" document for review of patient reports was found, however no documentation for 2017 and 2018 was found. 2. The Surveyor requested the laboratory's quality assessment policy and procedure to include the postanalytic systems and 2017 and 2018 postanalytic quality assessment documentation from the TP. The TP confirmed the laboratory did not have any other quality assessment policy and procedures established and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/05/2018 at 11:01 AM.