

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2065598	(X3) Date Survey Completed 11/08/2019
Name of Provider or Supplier John K Wildemore Md, Llc	Street Address, City, State 744 West Lancaster Ave Suite 230, Wayne, 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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the histology technology (HT), the laboratory failed to have safety data sheets (SDS) accessible to ensure protection from physical, chemical, biochemical, and biohazardous reagents and stains store in the laboratory from 2017 to the date of survey. Findings Include: 1. On the day of survey, 11/08/2019, the HT could not provide SDS to ensure protection from physical, chemical, biochemical, and biohazardous reagents and stains for the list below from 12/22/2017 to 11/08/2019. - Avantik Biogroup, 95% reagent alcohol. - Avantik Biogroup, 100% reagent alcohol. - Avantik Biogroup, scotts tap water. - Avantik Biogroup, eosin working solution. - Avantik Biogroup, hematoxylin gills III stain. - Avantik Biogroup, tissue marking dye (red). - Avantik Biogroup, tissue marking dye (yellow). - Avantik Biogroup, tissue marking dye (blue). 2. The HT confirmed the findings above on 11/08/2019 around 10:15 am.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:
Based on observation of reagents and interview with the histology technologist (HT), the laboratory failed to label and indicate reagents and stains with the appropriate open dates and other pertinent information required for proper use in 2017 to the date of survey. Findings Include: 1. On the day of survey, 11/08/2019, observation of reagents and stains in use, revealed that the laboratory did not record open dates of the following reagents and stains below: - 1 of 1, gallon bottle of Avantik Biogroup, 95% reagent alcohol. - 1 of 1, gallon bottle of Avantik Biogroup, 100% reagent alcohol. - 1 of 1, gallon bottle of Avantik Biogroup, scotts tap water. - 1 of 1, 32 oz bottle of Avantik Biogroup, eosin working solution. - 1 of 1, 32 oz bottle of Avantik Biogroup, hematoxylin gills III stain. - 2 of 2, 2 oz bottle of Avantik Biogroup, tissue marking dye (red). - 1 of 1, 2 oz bottle of Avantik Biogroup, tissue marking dye (yellow). - 1 of 1, 2 oz bottle of Avantik Biogroup, tissue marking dye (blue). 2. The laboratory was unable to provide pertinent information regarding 1 of 1 bottle of unlabeled solution, thought to be Toluidine blue stain. 3. The HT confirmed the findings above on 11/08/2019 around 10:00 am. *** oz = Ounce

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on observation of laboratory reagents and interview with the histotechnologist (HT), the laboratory failed to ensure that Avantik Biogroup, tissue marking dyes (2 of 5 bottles) were not used beyond their expiration date. Finding Include: 1. On the day of survey, 11/08/2019, observation of laboratory reagents revealed, the below Avantik Biogroup, tissue marking dyes (2 of 5 bottles) had expired in 2017: - Avantik Biogroup, tissue marking dye (red), Lot# 42664, Expired: 10/2017. - Avantik Biogroup, tissue marking dye (yellow), Lot#042825 , Expired: 10/2017. 2. The HT confirmed the finding above on 11/08/2019 around 10:00 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 review of the laboratory's procedure manual, maintenance records and interview histology technologist (HT), the laboratory failed to document the maintenance activities specified in their procedure manual for 1 of 1 Leica DM 750 microscope used for mohs microscopic examination in 2018. Findings Include: 1.

According to the Laboratory's microscope maintenance policy signed by the Laboratory Director, " 3. Yearly preventive maintenance done by approved microscope company." 2. On the day of survey, 11/08/2019, the laboratory could not provide documentation regarding preventive maintenance performed on 1 of 1 Leica DM 750 microscope in 2018. 3. In 2018, 300 patient slides were analyzed. 3. The HT confirmed the findings above on 11/08/2019 around 9:30 am.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on the review of patient test reports and interview with histology technologist (HT), the laboratory failed to include on mohs maps/test reports (2 of 2 reviewed) the location where mohs microscopic examination slides were read from 12/22/2017 to the date of survey. Finding Include: 1. On the day of survey, 11/08/2019, review of some test reports (2 of 2 reviewed), revealed that the test reports did not include the address where mohs microscopic examination slides were being read from 12/22/2017 to 11/08/2019. 2. In 2018, 300 patient slides were analyzed. 3. The HT confirmed the location where mohs microscopic examination slides were read are not included on mohs maps/test reports on 11/08/2019 around 10:30 am.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:

Based on review of the mohs microscopic examination procedure manual and interview with the histology technologist (HT), the laboratory director failed to ensure an approved procedure manual was available for mohs microscopic examination from 2017 to the date of survey. Findings Include: 1. On the day of survey, 11/08/2019, review of the mohs microscopic examination procedure manual revealed, the manual listed a different laboratory name (Main Line Dermatology) than the laboratory being inspected (John K. Wildemore MD, LLC). 2. The surveyor was unable to distinguish if the mohs microscopic examination procedure was from the laboratory being inspected, or from another laboratory. 3. The HT confirmed the findings above on 11/08/2019 around 9:35 am.