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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 31D0867580 | (X3) Date Survey Completed 12/04/2019 |
| Name of Provider or Supplier Grace U Chung, Md Pc | Street Address, City, State 500 Grove St, Haddon Heights, NJ | |
| 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 |
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| D5028 | <p>HISTOPATHOLOGY CFR(s): 493.1219</p> <p>If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of Quality Control records (QC), observation of reagents and interview with the Office Manager (OM), the laboratory failed to ensure that quality systems for the analytic phase of Histopathology testing were monitored from 12/12/18 to the date of survey. 1. The laboratory did not define an acceptable temperature range for the Leica Cryostat. Cross Refer to D5413. 2. The laboratory did not ensure Reagents were labeled with preparation and expiration dates. Cross Refer to D5415 3. The laboratory did not ensure Reagents were not used past their expiration dates. Cross Refer to D5417 4. The laboratory did not document all control procedures performed. Cross Refer D5601 5. The laboratory did not maintain an information or record system. Cross Refer D5787(b)</p> |
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Competency Assessment (CA) records and interview with the Office Manager (OM), the laboratory failed to perform a CA on four out of four</p> |

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| | <p>testing personnel for the calendar year 2018 to the date of survey. The OM confirmed on 12/4/19 at 9:40 am that the CA was not performed as stated above. This was previously cited. The Plan of Correction dated 1/29/18 stated "Completed Competency evaluation on personnel 1/3/18"</p> |
| D5217 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Biannual Assessment (BA) records and interview with the Office Manager (OM), the laboratory failed to verify the accuracy of Potassium Hydroxide (KOH) testing twice annually in the calendar year 2018 to the date of survey. The OM confirmed on 12/4/19 at 11:50 am the laboratory did not perform BA twice annually.</p> |
| D5291 | <p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Office Manager (OM), the laboratory failed to establish a written procedure for Biannual Assessment (BA) of Mohs and Potassium Hydroxide (KOH) tests from 12/12/17 to the date of survey. The OM confirmed on 12/4/19 at 10:55 am that a BA procedure was not established for the above mentioned tests.</p> |
| D5413 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Temperature Log (TL) and interview with the Office Manager (OM), the laboratory failed to define an acceptable temperature range for the Leica Cryostat used in Histopathology tests from 12/12/17 to the date of the survey. The OM confirmed on 12/4/19 at 10:40 am that an acceptable range was not defined.</p> |
| D5415 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</p> |

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| | <p>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> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of Potassium Hydroxide (KOH) bottle, and interview with the Office Manager (OM), the laboratory failed to put an expiration date on the KOH reagent bottle used for KOH testing on the date of survey. The OM confirmed on 12/4/19 at 11:10 am the laboratory failed to put an expiration date on the reagent.</p> |
| <p>D5417</p> | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of reagents and interview with the Office Manager (OM), the laboratory failed to discard expired reagents used for Histopathology tests on the date of the survey. The findings include: 1) Gills Hematoxylin 3 Lot 048303 expired 2/18. 2) Approximately 830 patients were run and reported. 3) The OM confirmed on 12/4/19 at 12:10 pm that the laboratory used an expired reagent.</p> |
| <p>D5601</p> | <p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to document Gill 3 Hemotoxylin stain quality used for Mohs slides from 12/12/17 to the date of survey. The OM confirmed on 12/4/19 at 11:30 am that the QC was not documented. This was previously cited. The Plan of Correction dated 1/29/18 stated "The lab is documenting all procedures performed, stains, with reactions".</p> |
| <p>D5787</p> | <p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the</p> |

following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
(a) Based on the lack of an Accession Log (AL) and interview with the Office Manager (OM), the laboratory failed to maintain an AL for Potassium Hydroxide (KOH) test from 12/12/17 to the date of survey. The OM confirmed on 12/4/19 at 11:15 am that the laboratory did not maintain an AL for KOH. (b) Based on surveyor review of the Test Records (TR) and interview with the OM, the laboratory failed to maintain accurate TR for Histopathology testing from 11/15/18 to the date of survey. The findings include: 1. A review of ten patients TR revealed ten of ten were not accurate as follows: a. Ten out of ten patients had no patient name, Date Of Birth (DOB), specimen site, tumor type, and no date of procedure . 2. The OM confirmed on 12/4/19 at 12:00 pm that the laboratory did not maintain an accurate TR.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on an surveyors review of the laboratory's records, procedures and interview with the Office Manager (OM), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 12/12/17 to the date of the survey. 1. The LD failed to ensure employee competency was assessed. Cross Refer to D5209. 2. The LD failed to evaluate the performance of KOH testing. Cross Refer to D5217.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM), the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with all the required elements for Testing Personnel from 12/12/17 to the date of survey. The OM confirmed on 12/4/19 at 9:30 am that a CA procedure was not established.