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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 33D0158521 | (X3) Date Survey Completed 04/10/2018 |
| Name of Provider or Supplier Mohammed S Hossain Md | Street Address, City, State 126 Hospital Road, Patchogue, NY | |
| 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 |
|---------------------------|---|
| D5417 | <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's observation of the laboratory's testing area, review of records and an interview with the laboratory director/testing person, the laboratory was using testing materials beyond manufacturer's expiration date. FINDINGS: 1. Surveyor observed 1 bottle of 32 oz Sigma -Aldrich Wright Stain, lot # 8154V expiration date September 2015 and 1 bottle of Sigma-Aldrich Wright Stain, lot # 8241V expiration date 1/2/2017 in the laboratory testing area. 2. On 4/10/2018 at approximately 12:30 PM, the laboratory director/testing person confirmed surveyor findings that the laboratory used expired Wright Stain to prepare differential slides from January 2017 to survey date. The laboratory director/testing person confirmed that an in-date container of Wright Stain was not available for use. 3. Approximately 155 patients were tested and reported for manual differentials using the expired Wright Stain reagent from January 2017 to survey date.</p> |
| D6094 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by:</p> |

Based on a surveyor review of the quality assessment (QA) program and confirmed in an interview with the laboratory director/testing person at the time of the survey, the laboratory director failed to ensure that the laboratory's QA program was maintained as part of the laboratory's overall quality systems program. Refer to D5417 PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON 11/3/2016.