

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1002586	(X3) Date Survey Completed 09/10/2019
Name of Provider or Supplier Hematopathology Associates Llc	Street Address, City, State 805 Executive Center Dr W Suite 300, Saint Petersburg, FL	
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
D0000	An announced CLIA initial survey was conducted at Hematopathology Associates on 09/10/2019. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) and American Proficiency Institute (API) proficiency attestation sheets and interview with the Director of Compliance, the Laboratory Director failed to sign the attestation sheets for four (CAP Microbiology D1 panel 2018 3rd Event and 2019 1st Event and CAP Microbiology D8 panel 2018 3rd Event and 2019 1st Event) out of eight (CAP Microbiology D1 and D8 panels 3rd Event 2018, CAP Microbiology D1 and D8 panels 1st and 2nd Events 2019 and API Microbiology 1st and 2nd Events 2019) panels reviewed. Findings Included: Review of the CAP microbiology proficiency records revealed the laboratory was enrolled in two different microbiology panels. D1 panel was for Coagulase negative Staphylococcus sp., Staphylococcus aureus, Staphylococcus epidermidis, and Streptococcus pyogenes. D8 panel was for Escherichia coli, Staphylococcus aureus, and Streptococcus agalactiae. Review of the API microbiology proficiency records showed the laboratory was enrolled with 4 API panels. API - Mycology was for Acremonium species, Aspergillus flavus, Aspergillus fumigatus, Aspergillus niger, Aspergillus terreus, Aspergillus versicolor, Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis, Epidermophyton floccosum, Fusarium solani, Microsporum audouinii, Microsporum</p>

canis, Scopulariopsis species, Trichophyton mentagrophytes, and Trichophyton rubrum. API - Candida Culture was for Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, and Candida tropicalis. API-Ectoplasm pneumonia was for Ectoplasm pneumonia. API - Blood Pathogen was for Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, and Candida tropicalis, Acinetobacter baumannii, Coagulase - negative Staphylococcus species, Staphylococcus epidermidis, Enterococcus faecalis, Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Proteus species, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus pyogenes, Klebsiella pneumoniae carbapenemase, mecA (gene responsible for methicillin resistance), New Delhi metallo-B-lactamase, VanA (type of Vancomycin resistance gene) and VanB(type of Vancomycin resistance gene). Review of the CAP attestation sheet for the D1 and D8 panels 3rd testing event in 2018 and the 1st testing event in 2019 revealed that Testing Personnel #B had signed as the Laboratory Director designee on the attestation sheet that affirms to the fact that proficiency samples were treated in the same manner as patient specimens. Testing Personnel #B did not qualify to be designated the Laboratory Director designee. Testing Personnel #B had been delegated to submit proficiency testing results. Interview on 09/10/19 at 10:30 am with the Director of Compliance confirmed that the Laboratory Director failed to sign the attestation statements for the CAP Microbiology D1 and D8 3rd testing event in 2018 and CAP Microbiology 1st testing event in 2019 and Testing #B was not qualified to be the Laboratory Director designee.