

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 09D0968273	(X3) Date Survey Completed 11/20/2020
Name of Provider or Supplier Dc Dfs Public Health Laboratory	Street Address, City, State 401 E Street Sw, Washington, DC	
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	Federal Jurisdictional Survey The laboratory is on compliance with 42 CFR part 493 with standard level deficiencies cited:
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, review of documentation for both the microbiology and Laboratory Response Network (LRN) sections, and interview with section supervisors, the laboratory failed to document incubation time frames and read times of microbiology plates to ensure that they were reviewed according to manufacturer's instructions of 18-24 hours as evidenced by: 1. In review of the microbiology media package inserts that the laboratory uses it states the following: BD TSA soy agar with 5% sheep blood, "Examine plates after 18-24 h for growth, colony size and hemolytic reactions." BD MacConkey agar, "Examine plates after 18-24 h for growth, colony size, pigmentation and selectivity." BD Chocolate agar, "Examine plates after 18-24 and 48 h for growth." 2. In review of documentation for both the microbiology lab and the LRN, the laboratory did not document times when patient samples plated on BD TSA soy agar with 5% sheep blood, BD MacConkey agar, and BD Chocolate agar were started to be incubated and when they were read to determine colony growth. The following patients worksheets were reviewed: patient 20-0099, subbed on BAP, MAC, Choc, on 11/4/2020 no time of incubation, no time when culture was read to ensure 18-24 growth on 11/5/2020. patient 20-0100, subbed on BAP, MAC, Choc, on 11/4/2020 no time of incubation, no time when culture was read to ensure 18-24 growth on 11/5/2020. patient 20-0101 subbed on BAP, MAC,</p>

Choc, on 11/4/2020 no time of incubation, no time when when culture was read to ensure 18-24 growth on 11/5/2020. patient #2009170390 subbed on BAP, MAC, Choc on 09/17/2020 no time of incubation, no time when when culture was read to ensure 18-24 growth on 9/18/2020. patient 200924098 subbed on BAP, MAC, Choc on 9/24/2020 no time of incubation, no time when when culture was read to ensure 18-24 growth on 9/25/2020. 3. In interview with the Microbiology section supervisor on 11-9-2020 @1044 she stated that they did not have the time documented when the plates started to be incubated and the when the plates were read. 4. In interview with the LRN section supervisor on 11-10-2020 @0921 she also stated that the LRN lab doesn't document the time when plates were started and read.

D5415

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

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.

This STANDARD is not met as evidenced by:
Based on direct observation, manufacturer's instructions, and interviews, the laboratory failed to indicate the new open vial stability date and preparation date on BD Gram's iodine reagent as evidenced by: 1. In review of the manufacturer's BD Gram stains kits and Reagents instructions states, "Use the traditional Gram iodine working solution within 3 months of preparation, not exceeding the expiry of either component." 2. In direct observation on 11-19-2020@0952, the Gram's iodine did not have an new vial stability date (3 months) or a date of preparation. 3. In interview with testing person #3 (on CMS-209) on 11-19-2020@0953, she stated, "We usually open the Gram's stains as a set, I think we opened the set on 11-3-2020." 4. In a follow-up question with testing person #3 on 11-19-2020 @0954 she was asked when the iodine reagent expired when it was opened. She thought it was the open date provided by the manufacturer on the label. She was unaware of the manufacturer's 3 month new vial stability date that was indicated by the manufacturer's instructions.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory's Quality Control (QC) documentation in Laboratory Response Network (LRN) , interview with the section supervisor, the laboratory failed to document actual QC reaction results for gram stain, catalase, oxidase, indole, and other biochemical results on 11-3-2020 as evidenced by: 1. In review of the laboratory's QC BT worksheet on 11-3-2020 the laboratory did not document the actual reactions of the QC organism tested, they wrote the following: Gram stain: QC Okay Catalase : QC Okay oxidase : QC Okay indole : QC Okay urea: QC Okay motility: QC Okay 2. In interview with the LRN section supervisor, on 11-20-2020

@0930 she stated that the laboratory could do better on documentation. She confirmed the finding.