

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0907678	(X3) Date Survey Completed 08/21/2025
Name of Provider or Supplier Medical Specialists Of The Palm Beaches Inc	Street Address, City, State 5401 S Congress Ave Ste 105d, Atlantis, 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 recertification survey was conducted at Medical Specialists of the Palm Beaches Inc on August 19 to August 21, 2025. The laboratory was not in compliance with 42 CFR, Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to document incubation time in and time out for urine culture testing from October 2023 to August 19, 2025, before patient testing. Findings Include: 1. Review of Urine culture Procedure created on 7/20/22 read, "incubate plates aerobically at 35-37 Celsius (C) for 18 -24 hours (H)." 2. Review on incubation log revealed no documentation of time in and time out for urine culture testing from October 2023 to August 19, 2025. 3. Review of Urine Culture Log Form revealed 331 patients were tested for urine culture from June 3, 2025 to August 19, 2025. 4. On 8/20/2025 at 5:00 PM, the Laboratory Director confirmed there was no documentation of incubation time in and time out for urine culture testing from October 2023 to August 19, 2025.</p>
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

(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, interview, and record review, the laboratory failed 3 out of 3 patients who were tested for international normalized ratio (INR), Prothrombin Time (PT/Protime), and APTT (Activated Partial Thromboplastin Time) with expired coagulation blood tubes. Findings include: 1. On 8/19/25 at 12:36 PM, the phlebotomy area had 12 Coagulation Sodium Citrate 3.2% that had expired on 8/01/25. Observation of the specimen's refrigerator revealed the following: a. Patient 1's specimen was collected on 8/13/25 with Coagulation Sodium Citrate 3.2% that had expired on 8/01/25. b. Patient 2's specimen was collected on 8/14/25 with Coagulation Sodium Citrate 3.2% that had expired on 8/01/25. c. Patient 3's specimen was collected on 8/14/25 with Coagulation Sodium Citrate 3.2% that had expired on 8/01/25. 2. Review of Patient Reports revealed the following: a. Patient 1's specimen was collected on 8/13/25 at 3:34 PM, and tested on 8/14/25 at 8:58 AM, for Protime, INR and APTT. b. Patient 2's specimen was collected on 8/14/25 at 8:09 AM, and tested on 8/14/25 at 1:41 PM, for Protime, INR and APTT. c. Patient 3's specimen was collected on 8/14/25 at 9:30 AM, and tested on 8/14/25 at 1:43 PM, for Protime, INR and APTT. 3. Review of Quality Management Plan created on 7/15/22 revealed there was no policy for expired reagents and blood specimen tubes. 4. On 8/20/25 at 5:00 PM, the Laboratory Director confirmed the laboratory failed 3 out of 3 patients who were tested for Protime, INR and APTT with expired coagulation blood tubes.

D5471

CONTROL PROCEDURES

CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.

This STANDARD is not met as evidenced by:

Based on interview, and record review, the laboratory failed to document and identify positive and negative reactivity before patient testing for each batch of media used in urine culture testing from October 2023 to August 19, 2025. Findings Include: 1. Review of Urine Culture Procedure approved on July 20, 2022 read, "Two levels of controls are performed on each new shipment of media before patient testing occurs. Results are recorded in the media culture quality control (QC) folder and reviewed by Lab Manager." 2. Review of Quality Assurance log sheet read, "Accepting a Batch: Presence of this QC sticker indicates that all relevant quality control has been performed (Note: Mueller Hinton, all QC products, and all discs must have additional on-site performance tests)." 3. Review of Quality Assurance Log Sheet revealed no identification on what was used as a negative control, positive control and blood agar media in batches and if controls passed from October 2023 to August 19, 2025. 4. Review of Urine Culture Log Form revealed 331 patients were tested for urine culture from June 3, 2025 to August 19, 2025. 5. On August 20, 2025 at 5:00 PM, the Laboratory Director confirmed there was no documentation to identify positive and

negative reactivity before patient testing, for each batch of media used in urine culture testing from October 2023 to August 19, 2025.