Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	08D2099470	02/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Green Clinics Laboratory	1633 Sorghum Mill Road, Dover, DE	

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	A Recertification Survey was conducted on February 24, 2026 at approximately 9:30 AM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows:
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (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. This STANDARD is not met as evidenced by: Based on facility policy/procedure review, facility document review, record review, and interview, the facility failed to document the reactions of histopathology quality control (QC) slides for immunohistochemical (IHC) and special stains each day of use for 19 of 19 patient reports reviewed. Findings included: A facility policy/procedure titled, "Standard Operating Procedure (SOP) IHC Staining Protocol," dated 04/26 /2016, revealed, "Section 4.8 Quality Control" revealed there was no procedure for documenting the reactions of the QC slides for IHC stains each day of use. A facility policy/procedure titled, "Standard Operating Procedure (SOP) Alcian Blue and PAS [Periodic Acid Schiff; a stain used to detect acid and neutral mucins] Staining Protocol," dated 04/18/2016, revealed there was no procedure for documenting the reactions of the QC slides for those stains for each day of use. A facility policy /procedure titled, "Standard Operating Procedure (SOP) Trichrome [a stain that uses three different dyes to detect muscle, collagen fibers, and cell nuclei] Staining Protocol for Connective Tissues," dated 04/19/2016, revealed there was no procedure for documenting the reactions of the QC slides for those stains for each day of use. A

	facility policy/procedure titled, "Standard Operating Procedure (SOP) GMS [Grocott's Methenamine Silver; a special stain used to detect fungi] Staining Protocol," dated 04/25/2016, revealed there was no procedure for documenting the reactions of the QC slides for those stains for each day of use. "Quality Control: Special Stains" documentation logs for "Grocott's Methenamine Silver," "Trichrome," and "Alcian Blue PAS [AB/PAS]" stains revealed the reactions of the QC slides were not being documented for each day of use. The documentation revealed a page for each stain with entries for "1/2026" and "2/2026." Patient reports special stains and/or IHC stains were used to render a diagnosis on the dates indicated, but there was no QC documentation for the day of use slides for the following: - Patient #1- Reported 05/05/2025- IHC - Patient #2- Reported 05/12/2025- IHC, AB/PAS, Trichrome - Patient #3- Reported 06/10/2025- IHC, AB/PAS - Patient #4- Reported 06/10/2025- IHC - Patient #5- Reported 07/03/2025- IHC - Patient #6- Reported 07/13/2025- IHC, AB/PAS - Patient #7- Reported 08/10/2025- IHC, Trichrome - Patient #8- Reported 08/27/2025- IHC - Patient #9- Reported 09/16/2025- IHC, AB/PAS - Patient #10- Reported 09/17/2025- GMS - Patient #11- Reported 09/23/2025- IHC - Patient #12- Reported 10/06/2025- IHC, AB/PAS - Patient #17- Reported 10/28/2025- GMS - Patient #13- Reported 11/06/2025- GMS - Patient #14- Reported 11/11/2025- IHC - Patient #15- Reported 12/04/2025- IHC - Patient #16- Reported 12/08/2025-GMS - Patient #19- Reported 01/13/2026- GMS - Patient #18- Reported 02/17/2026- IHC, AB/PAS During an interview on 02/24/2026 at 11:10 AM, Technical Supervisor (TS) #1 stated that in the past, the reactions for the QC slides were documented each day of use, but currently, only an entry made to indicate the QC slides were acceptable for the entire month. TS #1 further stated that if a special stain was ordered, there was a QC slide prepared, and she read it first to assess the stain quality and then initialed the slide to indicate the slide was reviewed and found to be acceptable. She stated that the Laboratory Director (LD) then reviewed the QC slide and initialed the slide to indicate the stain was acceptable. In regard to the process for documenting the review of the QC slides for the IHC stains, TS #1 stated that a positive and negative control was ran each day of use for IHC stains, and she and the LD documented their acceptance of the stain quality by initialing the slides. TS #1 stated that a documentation log was not kept of the reactions of the IHC stains for each day. During an interview on 02/24/2026 at 2:20 PM, the LD stated that daily documentation in a log was not being completed for each day of use and stated that he thought initialing the slides was an acceptable form of documentation.