

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1093025	(X3) Date Survey Completed 02/06/2024
Name of Provider or Supplier Faith Medical & Gastroenterology Center	Street Address, City, State 1845 W Army Trail Rd, Addison, IL	
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
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(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. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures, patient test records, quality control (QC) logs and interviews with the laboratory representative; the laboratory failed to document QC reviews for six out of six patient results utilizing immunohistochemical (IHC) stain and five out of five patient results utilizing special staining reviewed in the years of 2022 and 2023. Findings include: 1. Review of the laboratory's procedure manual identified the procedure "General Workflow", which stated under "E. Quality Control and Improvement", "Pathologist reviews slides for stain quality and tissue representation prior to reading any cases. Quality control forms are completed and filed in the QC binder by date indicating stain quality is acceptable." 2. Upon review of the laboratory's policies and procedures, under "Frequency and Records of Quality Control Analyses", it's stated, "All immunohistochemistry [IHC] and special stain slide quality control [QC] is assessed and documented on a case by case basis. Any slide that does not pass the quality assessment by the pathologist will be repeated until the quality of the staining is deemed acceptable." This document also stated, under "Post-analytical Quality Control Procedures", "The results of control tissue for the special stains should be recorded when appropriate." 3. Upon review of the laboratory's Quality Assessment Plan, under "Quality Control", it's stated, "We document the results of all controls and will take appropriate actions when the controls do not perform as expected." 4. Upon review of patient test records and the</p>

corresponding QC logs, it was revealed that six out of six patient results utilizing IHC stain failed to have positive and negative reactivity results documented prior to reporting patient results. Patient Accession #: Date of testing: IHC Stain: AC844899 03/22/2022 H. pylori RANBA000 08/06/2022 CD3 PS925894 02/18/2023 H. pylori RB186497 06/17/2023 CD3 ER792219 09/02/2023 H. pylori MS486706 11/27/2023 CD3 5. Upon review of patient test records and the corresponding QC logs, it was revealed that five out of five patient results utilizing special staining failed to have a control slide of positive reactivity documented prior to reporting patient results. Patient Accession #: Date of testing: Special Stain: RANBA000 08/06/2022 PAS/Alc Blue PS925894 02/18/2023 PAS/Alc Blue RB186497 06/17/2023 PAS/Alc Blue ER792219 09/02/2023 PAS/Alc Blue MS486706 11/27/2023 PAS/Alc Blue 6. On survey date 02/06/2024, and 3:03 pm, a laboratory representative verified the above findings.