Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1086601	11/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Advocate Good Samaritan Immediate Care & Outpt Ctr	6840 Main Street, Downers Grove, 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
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manuals; laboratory records; Proficiency Testing (PT) records; and interview with Technical Consultant, the laboratory failed to retain a copy of test procedures for its Chem 8 panel tests that includes the dates of initial use and discontinuance. Findings: 1. Laboratory documentation shows that the laboratory was notified by the manufacture of the I-Stat (Abbot) in December 2019 that Chem 8 blue panel may not perform as intended. 2. On survey date November 4, 2020 at 10:00 AM, the Technical Consultant told the surveyor that the laboratory ceased testing of the Chem 8 panel from January 2020 to October 2020. 3. Review of laboratory records from January 2020 to October 2020 revealed that the laboratory reported only Complete Blood Counts (CBCs) and creatinine test results. 4. There was no documentation to show the initial use, discontinuance, and reinstatement of Chem 8 testing. 5. On November 4, 2020 at 11: 30 AM, the Technical Consultant confirmed the surveyor's findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions

	for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures manuals; observations; and interview with Testing Personnel and the Technical Consultant, the laboratory failed to establish and follow written policies and procedures for specimen processing. Findings include: 1. There were no policies and procedures that described the laboratory's process for processing specimens. 2. The surveyor observed that specimens were logged on a specimen receipt log. 3. On November 4, 2020 at 11:00 AM, the surveyor asked Testing Personnel how specimens are logged in. Testing personnel told the surveyor that the nurses from immediate care log in the send out specimens, and sometimes they log in specimens from this lab, "but not all the time." The surveyor asked Testing Personnel where the specimen logs are stored. Testing Personnel told the surveyor that they only keep 3 months of specimen logs. After 3 months, the specimen logs are shredded. 4. On November 4, 2020 at 11:30 AM, the Technical Consultant told the surveyor that she had no idea that testing personnel were logging specimens. 5. On November 4, 2020 at 11:35 AM, the Technical Consultant confirmed the surveyor's findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures manuals; email notification, and interview with the Technical Consultant, procedures for the CHEM 8 panel for the Istat analyzer were not approved, signed and dated by the current laboratory director before use. Findings include: 1. There were no written procedures approved, signed, and dated by the laboratory director for performance of Chem 8 testing on the Istat. 2. Review of email dated Wednesday, October 14, 2020 at 4:57 PM, revealed someone in the finance department gave the all clear to begin testing with the Istat analyzer for testing of the Chem 8 Panel. 3. The email notification states, "I have the all clear from ...We are ready to go live with i-Stat testing using the Chem 8+ cartridge. This will start the morning of Friday, Oct 16, 2020." 4. In an interview with the Technical Consultant November 4, 2020 at 11:30 AM, the Technical Consultant told the survey that the person giving the "all clear to begin testing" works in the finance department, not the laboratory. 5. On November 4, 2020 at 11:35 AM, the Technical Consultant confirmed the surveyor's findings.