Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2079014	06/26/2020
Name of Provider or Supplier	**Street Address, City, State**	
Asap Lab	4350 Oakes Rd Suite 513, Davie, 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 unannounced complaint survey conducted on 6/24/2020 through 6/26/2020 found that ASAP LAB clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following conditions were not met: D6076- Laboratory Director D3000- Facility Administration
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure that the testing laboratory reported positive and negative COVID-19 results to the Florida Health Department from March 2020 to June 2020. Findings Include : -Refer to 3009 - During an interview on 06/24/2020 at 12:30 pm with the owner confirmed that the laboratory does not have records of the notification to the Florida Health Department of positive and negative results.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure that the

	testing laboratory reported positive and negative COVID-19 results to the Florida Health Department from March 2020 to June 2020. Findings Included: -Review of email between owner and Laboratory Director (LD) from the reference laboratory on date 6/24/2020, revealed that the testing laboratory stated that they reported only positive results for patients that they had full demographic information. -No records available for documentation of reports to the Florida Health Department of Covid-19 for positive and negative results. -Review of FDOH Emergency Rule 64DER20-26 (64D-3.029) of April 10th 2020, revealed for COVID-19; the timeframe is immediately and had special reporting requirements. Results should be reported and accompanied by any testing conducted (positive and negative). For laboratories performing electronic laboratory reporting as described in subsection 64D-3.031 (5). F. A.C., all test results (positive and negative) are to be submitted, including screening test results (positive and negative). -During an interview on 06/24/2020 at 12:30 pm with the owner confirmed that the laboratory does not have records of the notification to the Florida Health Department of positive and negative results .
D5207	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have a complaint policy for Covid-19 specimen samples sent to reference laboratory. Findings Included: A review of Quality Assessment record revealed there was no written complaint policy for Covid-19 specimen samples sent to reference laboratory. An interview on 6/26 /2020 at 2:33 pm with the owner confirmed that there was no complaint policy for Covid-19 specimen samples sent to reference laboratory.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to use Covid-19 requisitions with the current laboratory director A (LD A) instead of previous laboratory director B (LD B) from April 8th, 2020 to June 25, 2020. Findings Included: -A review of the CMS -209 laboratory personnel report signed on date revealed LD A, was the current director. -A review of Commission on Office Laboratory Accreditation(COLA) notification records, revealed that the laboratory had 3 different LD (LD A, LD B, LD C) since 3/01/2020 to 6/26/2020. -LD B has not been in this position since April 8th ,2020 as per the laboratory notifications sent to COLA on 4/15/2020. -A review of Covid-19 requisitions revealed LD B listed as LD on the top page from April 8th, 2020 to June 2020. -An observation of current 2020 Covid-19 specimen collection kits showed requisitions still had LD B listed as Laboratory Director. An interview on 6/26/2020 at 2:30pm with the owner confirmed

	that the laboratory used Covid-19 requisitions with LD B and not the current laboratory director (LD) since April 8th, 2020 to June 25, 2020.
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 observation, record review and interview, the laboratory failed to have a written policy for Covid-19 specimen collection preparation for Amies Transport Medium and specimen acceptability Covid-19 send outs for reference laboratory (RL). Findings Included: An observation on 6/25/20 at 10 am of Molecular room revealed Technologist A (TA) was transferring sterile saline out of tube. TA placed 3 ml of Amies Transport Medium into the same tube. She stated the method is another form of specimen collection for Covid-19. A review of specimen collection manual revealed no policy for how to transfer Amies Transport Medium into previous sterile saline tubes and specimen collection acceptability Covid-19 for RL accepts. Interview on 6/26/2020 at 2:33pm with the owner confirmed that there was no policy Covid-19 specimen preparation collection for Amies Transport Medium and specimen acceptability for the RL.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on record review and Interview the laboratory failed to create accession log and shipping log that documents the time and date of Covid-19 samples from March 23, 2020 to June 26,2020. Findings Included: A review of accessioning policy displayed that Covid-19 samples sent out must be recorded on an excel spreadsheet for that day. A review of specimen received, and shipping log revealed no documentation for received and send out days for Covid-19 samples from March 23, 2020 to June 26, 2020. An Interview on 6/26/2020 at 2:33pm, with the owner confirmed that the lab was not documenting received and shipping dates and times for Covid 19 specimen from March 23, 2020 to June 2020.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to create a quality assessment (QA) policy for the review of test reports that ensure final reports have the current Laboratory Director (LD) named from 4/15/2020 to 6/26/2020. Findings Included: -Review QA policy revealed no written documentation on reviewing final test reports. -Review of LD notification change to COLA on 4/15/2020 revealed that the laboratory changed from LD B to LD C. -Review of final report for patient case number 53896 (collection date 5/30/2020), 109229 (collection date 5/4/2020) and case 159041 (collection date 5/29/2020) revealed that LD listed was LD B. -During an interview on 06/24/2020 at 12:30 pm with the owner confirmed the laboratory failed to update the LD name on final reports listed above.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the Laboratory failed to have qualified Laboratory Director (LD) (LD B and LD C) from 03/01/2020 to 6/10/2020 (See 6078). The Laboratory Director (LD A, LD B and LD C) failed to have oversight of the laboratory (See 6079). The LD (LD A, LD B and LD C) failed to provide onsite, telephone or electronic consultation (See 6080). The LD (LD A LD B and LD C) failed to ensure that an approved procedure manual was available (See 6106).
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience

	directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on record review and staff interview. The laboratory failed to have qualified LD from 3/01/2020 to 6/10/2020 for the Microbiology specialty. Findings Include: Review of laboratory notifications to COLA accreditation organization, revealed that the laboratory added the specialty of Microbiology to the test Menu on 3/01/2020 and change to LD B on that date. The laboratory sent on 4/15/2020 a request for LD C and on 6/10/2020 for LD A (current LD). Review of Florida License for LD B and C, revealed that none of them have the Microbiology specialty in the Director License. During an interview on 06/26/2020 at 1:30 pm with Consultant # 2, she confirmed that LD B and C that acted as LD from 03/01/2020 to 06/09/2020 and that both acting LDs failed to have the Microbiology specialty in their Florida Director License.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and staff interview. The LD A, B and C failed to have oversight of the laboratory from 3/1/2020 to 6/26/2020. Findings Include: -See 5207. The Laboratory Director (LD) failed to ensure the laboratory had a complaint policy for the Reference laboratory for Covid-19 and respiratory panel samples. -The LD failed to ensure that the laboratory update in the requisitions and LIMS system the patient demographic; the laboratory input the demographic information into the LIMS system (See 5309); the laboratory failed to have a Covid-19 sample collection procedure (See 5311); the laboratory had a accessioning log for Covid-19 samples (See 5313). -See 5891 The LD failed to have a quality assessment policy for the review of test reports that ensured final reports have the current LD . -See 3009 The LD failed to ensure that the testing laboratory reported positive and negative COVID-19 results to the Florida Health Department from

	March 2020 to June 2020. During an interview on 06/26/2020 at 2:30 pm with the owner, he confirmed that LD A, B and C, failed to provide oversight in laboratory operations from 3/1/2020 to 6/26/2020.
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview. The LD failed to provide onsite, telephone or electronic consultation laboratory from 3/01/2020 to 6/26/2020. Findings Include: -There was no documentation of the consultation provided by the LD for the period reviewed -Review of the policies of the Procedure Manual provided during the inspection revealed that the LD A (current LD), B and C failed to sign the procedure manual for the laboratory for the period of time they acted as LD. During an interview on 06/26/2020 at 2:30 pm with the owner confirmed that the laboratory failed to show that the LD is providing consultation to the laboratory operation.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and staff interview. The LD A, B and C failed to sign the procedure manual of the laboratory from 03/01/2020 to 6/26 /2020. Findings Include: Review of the policies of the Procedure Manual provided during the inspection revealed that the LD A, B and C, failed to sign the procedure manual for the laboratory for the period of time they acted as LD. During an interview on 06/26/2020 at 1:30 pm with consultant # 2, she confirmed that LD A, B and C, failed to sign the procedure manual from 03/01/2020 to 6/26/2020.