

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2137040	(X3) Date Survey Completed 07/23/2019
Name of Provider or Supplier Labs Asap Llc DbA Nona Scientific	Street Address, City, State 1601 Ne 25th Ave Unit 103, Ocala, 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	A recertification survey was conducted on 7/23/19 at Labs ASAP Llc. The facility was not in compliance with 42 CFR 493, Requirements for CLIA.
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review of API (American Proficiency Institute) proficiency test records and interview with testing personal, the laboratory failed to test hematology proficiency samples the same number of times patient samples are tested for 3 testing events reviewed from 2018-2019. Findings Include: Review of the Complete Blood Count (CBC) instrument printout records for the API proficiency testing events showed the following: 1. The 2018 Hematology/Coagulation 2nd event kit had two printouts for each of the five CBC samples tested (HEM-6 - HEM-10). 2. The 2018 Hematology/Coagulation 3rd event kit had two printouts for each of the five CBC samples tested (HEM-11 - HEM-15). 3. The 2019 Hematology/Coagulation 1st event kit had two printouts for each of the five CBC samples tested (HEM-01 - HEM-05). The tests performed were: White Cell Count, Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, Mean corpuscular volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red cell distribution width (RDW), Neutrophils, Lymphocytes, Monocytes. Interview with the Technical Consultant on 7/23/19 at 11:45am confirmed hematology proficiency testing had been performed in duplicate.</p>
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p>

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the facility failed to have a passing proficiency test score for the analyte "Sodium" during the 1st Chemistry testing event in 2019. Findings include: The record review on 7/23/19 of the American Proficiency Institute 1st Chemistry event of 2019 showed a score of 60% for the analyte "Sodium" The 7/23/19 interview with the Technical Consultant at 12:15pm confirmed the failure in proficiency testing.

D2128

HEMATOLOGY

CFR(s): 493.851(e)

(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document remedial action for unsatisfactory proficiency testing results for one of two Hematology analyte unsatisfactory scores reviewed in 2018. Findings included: Review of American Proficiency Institute (API) proficiency testing results for 2018 showed that the lab had an unsatisfactory score on the following Hematology analyte and there was no documentation of remedial action: 60% on Mean Corpuscular Volume (MCV) for the 3rd Event of 2018 During an interview on 7/23/19 at 12:00pm, the Technical Consultant confirmed that there was no documentation of remedial action for the three unsatisfactory score.

D2130

HEMATOLOGY

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) proficiency testing results and staff interview, the laboratory had 2 out of 3 consecutive unsuccessful testing events for Mean Corpuscular Volume (MCV) in the specialty of Hematology. Findings Include: Review of API proficiency testing results found the 1st and 3rd testing event in 2018 had a 60% for MCV. During an interview on 7/23/19 at 12:00pm, the Technical Consultant confirmed the consecutive failures.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on review of API (American Proficiency Institute) proficiency testing results and interview with the Technical Consultant, the laboratory failed to document evaluation of proficiency testing results that were ungraded for the 1st Immunology testing event of 2019. Findings Include: Review of API proficiency testing results in the 1st testing event of 2019 showed a score of ungraded for Antistreptolysin O. During an interview on 7/23/19 at 12:10 PM, the Technical Consultant confirmed that the laboratory did not evaluate the ungraded score with the summary provided by API for the ungraded analyte.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) proficiency testing results for the first Chemistry Miscellaneous event of 2019 and interview with the Technical Consultant, the laboratory failed to have corrective action for the unsatisfactory testing event. Findings Included: Review of API proficiency testing results for the 1st Chemistry Miscellaneous event of 2019 showed a result of 67% for the analyte "Parathyroid Hormone". There was no documentation showing any corrective action was performed. During an interview on 7/23/19 at 12:15pm, the Technical Consultant confirmed the lack of documented corrective action.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(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 record review and staff interview, the facility failed to ensure weekly and monthly maintenance was performed on the TOSOH A1A 900 instrument for 4 months in 2019, and failed to ensure monthly maintenance was performed on the ActDif2 instrument for 3 months in 2019. Findings include: The maintenance record review of the TOSOH A1A 900 showed in April 2019, the monthly maintenance of "Clean sample area with ethanol", "Replace B/F wash probe tip", and "Replace wash /diluent reservoir filters" was not performed. The maintenance schedule in May 2019 showed the weekly maintenance of "Clean B/F wash probe tip" and "Clean substrate line with 70% ethanol x5" was only performed twice (5/7/19 and 5/24/19). In June 2019, the weekly maintenance was performed once on 6/14/19. In July 2019, the weekly maintenance was not documented as performed. The maintenance record

review of the AcTdif2 instrument showed the monthly maintenance of "Clean closed vial station & probe", and "Clean airfilter" was not documented as performed in March 2019, April 2019, and June 2019. The interview with the Technical Consultant on 7/23/19 at 1:47pm confirmed the maintenance was not documented.