

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2001422	(X3) Date Survey Completed 03/12/2020
Name of Provider or Supplier Jaro Company Llc	Street Address, City, State 1349 S Rochester Road Suite 210, Rochester Hills, MI	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to monitor laboratory room temperature and humidity for 2 (March 2018 to March 2020) of 2 years reviewed. Findings include: 1. A record review of the laboratory's temperature monitoring documentation revealed a lack of room temperature and humidity documentation for the laboratory. 2. A review of the laboratory's "Temperature Checks and Corrective Action" procedure revealed a lack of policy for the monitoring of laboratory room temperature and humidity. 3. A review of the laboratory's Leica DM500 microscope manufacturer's manual revealed a section titled "Operating Environment" stating, "Ambient temperature: 5 to 40 degrees Celsius (41 to 104 degrees Fahrenheit). Maximum relative humidity: 80% for temperatures up to 31 degrees Celsius, decreasing linearly through 70% at 34 degrees Celsius, 60% at 37 degrees Celsius, to 50% at 40 degrees Celsius." 4. A review of the laboratory's Leica Autostainer XL manual revealed a section titled "Technical Data" stating, "Operating temperature range: 15 degrees Celsius to 35 degrees Celsius. Relative humidity: max 80%, non-condensing." 5. A review of the laboratory's Leica RM 2255 Rotary Microtome manual revealed a section titled "Technical Data" stating, "Operating temperature range: +10 degrees Celsius to +35 degrees Celsius.</p>

	<p>Relative humidity: max 80% non-condensing." 6. An interview on 3/12/2020 at 10:15 am with TP1 confirmed the laboratory did not record laboratory room temperature and humidity.</p>
<p>D6122</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(ii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the Technical Supervisor failed to ensure testing personnel competency assessments included monitoring the recording and reporting of test results for 2 (March 2018 to March 2020) of 2 years. Findings include: 1. A review of the testing personnel competency assessment documents from March 2018 to March 2020 revealed a lack of an assessment of monitoring the recording and reporting of test results. 2. A review of the laboratory's "Histology Competency Procedure" revealed a lack of policy for monitoring the recording and reporting of test results. 3. An interview on 3/12/2020 at 10:20 am with TP1 confirmed the testing personnel competency assessments did not assess the monitoring of recording and reporting of test results.</p>
<p>D6126</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the Technical Supervisor failed to ensure testing personnel competency assessments included assessment of problem solving skills for 2 (March 2018 to March 2020) of 2 years. Findings include: 1. A review of the testing personnel competency assessment documents from March 2018 to March 2020 revealed a lack of an assessment of problem solving skills. 2. A review of the laboratory's "Histology Competency Procedure" revealed a lack of policy for the assessment of problem solving skills. 3. An interview on 3/12/2020 at 10:20 am with TP1 confirmed the testing personnel competency assessments did not assess problem solving skills.</p>
<p>D6168</p>	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.</p> <p>This CONDITION is not met as evidenced by: . Based on document review and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure personnel performing high complexity histopathology testing met educational requirements at 42 CFR 493.1489 for 1 (Testing Personnel #4)</p>

of 5 testing personnel. Findings include: 1. The laboratory failed to ensure testing personnel performing high complexity testing were qualified before performing testing. Refer to D6171.

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)

(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure testing personnel performing high complexity testing were qualified before performing histopathology testing for 1 (Testing Personnel #4) of 5 testing personnel listed on the CMS-209 form. Findings include: 1. A review of testing personnel credentials revealed a Bachelor of Arts degree for Testing Personnel #4. 2. An interview on 3/12/2020 at 11:13 am with TP1 revealed Testing Personnel #4 was performing high complexity tissue gross examinations. 3. The surveyor requested additional credential documentation on 3/12/2020 at 11:13 am. 4. An interview on 3/9/2020 at 1:50 pm with TP1 confirmed the credentials for Testing Personnel #4 were not available. 5. The laboratory was granted an additional 7 days to submit missing credentials to the surveyor and they were not made available.