Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0648131	04/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
Weland Clinical Laboratories,Pc	1911 First Avenue Se, Cedar Rapids, IA	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of Cobas 6000 chemistry calibration records, the Chemistry Calibration Policy and confirmed by laboratory personnel identifier #10 (refer to Laboratory Personnel Report) at approximately 2:40 pm on 04/03/2019, the laboratory failed to retain a copy of calibration records for the electrolytes: sodium, potassium, and chloride for 21 out of 24 months from 4/1/2017 - 4/1/2019. The findings include: 1. The Chemistry Calibration Policy (effective 4/5/2017) stated, "All calibration reports will be placed in a drawer and kept for 2 months. The calibration data is stored on our Cobas 6000 and is retrievable from the analyzer." 2. The laboratory had calibration records for the electrolytes: sodium, potassium and chloride from 2/1/2019 - 4/3/2019. 3. Laboratory Personnel identifier #10 confirmed that calibration records for sodium, potassium and chloride prior to 2/1/2019 could not be retrieved from the Cobas 6000 chemistry analyzer. 4. At the time of the survey, the laboratory did not have any additional calibration records for the electrolytes: sodium, potassium and chloride prior to 2/1/2019.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299.

	This CONDITION is not met as evidenced by: Based on review of Sysmex CS2500 coagulation reagent verification records from December 2018, observations of the coagulation analyzer and confirmed by laboratory personnel identifier #20 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 04/03/2019, the laboratory failed to meet the hematology (coagulation) requirements for test system/equipment/reagent verification as specified in the standard D5411.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of Sysmex CS2500 coagulation reagent verification records from December 2018, observations of the coagulation analyzer and confirmed by laboratory personnel identifier #20 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 04/03/2019, the laboratory failed to program the correct normal patient mean for lot number 549724, expiration date 11/16/20 of Prothrombin Time (PT) reagent into the Sysmex CS2500 coagulation analyzer. The findings include: 1. The laboratory must establish a normal patient mean with each new lot number of PT reagent. 2. For lot number 549724, expiration date 11/16/20 of PT reagent the laboratory established a normal patient mean of 10.3 seconds. 3. At the time of the survey, the laboratory had programmed into the Sysmex CS2500 coagulation analyzer the normal patient mean as 10.5 seconds. 4. Laboratory personnel identifier #20, confirmed the laboratory did not have the correct established normal patient mean programmed into the Sysmex CS2500 coagulation analyzer.
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined; This STANDARD is not met as evidenced by: Based on review of the laboratory's workload limit procedure and confirmed by laboratory personnel identifier #13 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 04/03/2019, the laboratory failed to establish and follow a written workload limits procedure that ensures the workload limits are established and the number of slides examined prorated based on an 8-hour workday for one out of one part-time cytotechnologist (identifier #30). The findings include: 1. Personnel identifier #13 stated that the laboratory hired personnel identifier #30 in December

	2018 as a part-time cytotechnologist and that personnel identifier #30 also worked at another location as a full-time employee. 2. Review of the workload limits procedure indicated that the laboratory based workload limit assessments for personnel identifier #30 on a maximum of 100 cytology slides in a 24-hour period, screened in an 8-hour period. 3. Personnel identifier #13 confirmed that the laboratory did not prorate the number of slides that may be examined by personnel identifier #30 at Weland Clinical Labs.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, laboratory records, interview with the Laboratory Operations Manager, and confirmed by laboratory personnel identifier #13 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 04/03/2019, the laboratory failed to establish and follow written policies and procedures to maintain records of the total number of gynecological and non-gynecological cytology slides examined by six out of 10 testing personnel (personnel identifiers #1 and #25-#29) who examine slides and the number of hours spent examining slides during each 24-hour period in 2018 and to the date of the survey in 2019. The findings include: 1. The Laboratory Operations Manager stated that personnel identifiers #1 and #25- #29 each examine gynecological and non-gynecological cytology slides for the laboratory. 2. At the time of the survey, personnel identifier #13 confirmed that the laboratory did not have a written policy or procedure for maintaining records of gynecological and non-gynecological slides examined and the time spent examining them for each individual during each 24-hour period. 3. At the time of the survey, personnel identifier #13 confirmed that the laboratory did not have records of gynecological and non-gynecological slides examined and the time spent examining them available for personnel identifiers #1 and #25-#29 from 2018 and up to the date of the survey in 2019.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of antimicrobial susceptibility testing (AST) quality control (QC) records, the Quality Control/Quality Management for Micro procedure and confirmed

	by the laboratory personnel, identifier #21 (refer to the Laboratory Personnel Report) at approximately 11:45 am on 4/3/2019, the laboratory failed to take and document corrective action when the gram positive combo 33 antimicrobial susceptibility testing QC fell outside the laboratory's established criteria for acceptability for one out of five weeks (8/22/2018) of testing in August of 2018. The findings include: 1. The Quality Control/Quality Management for Micro procedure (effective 10/1/2018) states, "If a weekly out-of-control result is due to an obvious error: -Use of the wrong control strain -Obvious contamination of the strain or the medium -Inadvertent use of the wrong incubation temperature or conditions Document the reason and retest the strain on the day the error is observed. If the repeated result is within range, no further corrective action is necessary." 2. For the gram positive combo 33 AST panel the laboratory performed weekly QC using the organism Staphylococcus aureus 29213. 2. On 8/22/2018 the laboratory had the following out of range AST quality control results for organism Staphylococcus aureus 29213: *Vancomycin = 0.25 (established range 0.5 - 2) 4. At the time of the survey, the laboratory did not document corrective action for the out of range QC.
D6168	TESTING PERSONNEL CFR(s): 493.1487 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. This CONDITION is not met as evidenced by: Based on review of personnel records and confirmed by the Laboratory Operations Manager at approximately 10:30 am on 04/03/2019, the laboratory fails to meet the educational qualification requirements for testing personnel who perform high complexity testing as specified in standard 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 review of the CMS-209 Laboratory Personnel Report, personnel records and confirmed by the Laboratory Operations Manager at approximately 10:30 am on 04/03/2019, the laboratory failed to meet the educational requirements for one out of 16 testing personnel reviewed (identifier #15, refer to the Laboratory Personnel Report) who perform high complexity testing. The findings include: 1. The Laboratory Personnel Report listed personnel identifier #15 as high complexity testing personnel. 2. The Laboratory Operations Manager stated that personnel identifier #15 performed grossing of tissue specimens in the histology department. 3. Review of education records indicated that personnel identifier #15 did not meet the educational requirements for high complexity testing personnel. 4. At the time of the survey, the laboratory did not have additional educational documentation to qualify personnel identifier #15 as high complexity testing personnel.