Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2058146	10/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Hometown Urgent Care Of Michigan, Pc Dba Wellnow	4903 South Emerson Ave Suite B, Indianapolis, IN	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to: a) ensure non-expired negative and positive controls (expiration 1/19/22 and 1/14/22) were used for five out of ten patients reviewed for COVID-19 testing. (refer to D5417); b) establish performance specifications for accuracy, precision, analytic sensitivity, analytic specificity, interfering substance, and specimen storage for one of one modified test (SARS- CoV-2 (COVID-19) RT PCR) prior to testing patient specimens on 12/15/2021 (refer to D5423); and c) validate research only positive and negative controls for analytical method of one of one test (SARS- CoV-2(COVID-19) RT PCR) prior to patient specimen testing on 12/15/2021 (refer to D5425).
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 observation and record review, the laboratory failed to ensure non-expired negative and positive controls (1/19/22 and 1/14/22) were used for five out ten patients (PT#5-PT#10) reviewed for COVID-19 testing. Findings included: 1.) During a tour of room "Lab A", on 10/4/2022 at 9:04 AM, revealed a freezer in use for COVID-19. The freezer contained the following open reagents in use: a.) Positive Control Lot: FG000161. The box states for "Research Use Only. Not for use in diagnostic procedures" (expiration 1/19/2022). b.) Negative Control Lot:NC051022. The box states for "Research Use Only. Not for use in diagnostic procedures" (expiration 1/14/2022 and 1/19/2022). c.) The reagents had no company name listed on the boxes. 2.) Review of Laboratory Quality Assurance Plan, signed by laboratory Director on 4/21/2021, states "Any expired material is discarded as outlined in the product's package insert or as indicated in an appropriate safety manual." Does not state the removal of material as soon as it expires. 3.) Review of CFX-96 instrument specimen plate run on 8/8/2022 revealed patients PT#5-PT#10 were tested for Covid-19 PCR. 4.) The annual COVID-19 testing volume is 100,000.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to establish performance specifications for accuracy, precision, analytic sensitivity, analytic specificity, interfering substance, and specimen storage for one of one modified test (SARS- CoV-2 (COVID-19) RT PCR) prior to testing patient specimens on 12/15 /2021 and for ten of ten patients (PT#1-PT#10) reviewed. Findings Included: 1.) During a tour of room "Lab A", on 10/4/2022 at 9:04 AM, revealed a freezer in use for COVID-19. The freezer contained the following open reagents in use: a.) Covid-19 94 panel plate lot#: FG000394 expiration on 8/8/2022 The reagent states for "Research Use Only. Not for use in diagnostic procedures." b.) Lysis buffer Lot#: FG000318 (Package insert states "Research Use Only. Not for use in diagnostic procedures.") c.) Positive Control Lot#: FG000161. The box states for "Research Use Only. Not for use in diagnostic procedures". d.) Negative Control Lot#:NC051022 The box states for "Research Use Only. Not for use in Diagnostic procedures". e) The reagents had no company name listed on the boxes. 2.) Review of reagent and control packaging slips revealed the following: a.) reagents and controls were sent from Precision Mircobio on 5/18/2022, 5/24/2022 and 1/25/2022. b.) reagents and controls were sent from Molecular Designs on 8/24/2022. c.) reagents and controls were sent from an unlisted company name on 6/7/2022, 6/21/2022 and 6/28/2022. 3.) Review of "Analytical Validation of SARS-CoV-2 (COVID-19) RT -PCR Assay Using Extraction Free Method", signed by Laboratory director on 11/12/2021, stated "this

	validation aims to establish that the SARS -CoV2 (COVID-19) duplex may be satisfactorily used as a diagnostic tool to access human samples for the n1 gene found in the SARS -CoV-2 genome and an endogenous control, Rnase P, which can be used to evaluate extraction efficiency on a Biorad CFX 96. The assay used in the validation were purchased from DoubleHelix Specialist, which contain all primers, probes, enzymes, and excipients premixed. See the product insert for assay- specific method." Product insert was not located in the documentation for the validation. The validation did not list the Federal Drug Administration (FDA) approved instructions for use (IFU) "Assurance SARS-CoV-2 Panel Extraction-less SOP for Partners Labs" as the method that was followed. The validation did not include reagents and controls purchased from other companies such as Precision Microbio or Molecular Designs that were for "Research Use Only." 5.) Review of Well Now Urgent Care "SARS-COV-2 laboratory Operating Procedure", signed by laboratory director on 5/5/2022, indicated the procedure the laboratory was following was EUA#200522 SARS-CoV-2 extraction Free Methodology along with Bio-Rad CFX96 and Ignite LIS. 6.) Review of CFX-96 instrument specimen plate runs on 12/15/2021 and 8/8/2022 displayed IC and Covid-19 as the targets for result determination. N1 and Rnase P were not listed as targets to determine patient results. 7.) During a tour of room "Lab B" on 10/4/2022 at 9:12 AM, displayed racks of unprocessed and completed tests of Covid-19 specimens in sterile normal saline collection tubes sitting on table at room temperature. 8.) Review of Sterile Normal Saline package insert states, revision date 2021.01, "it can preserve the viability of clinical specimens at 4 C for 72 hours without degradation. Best recovery is obtained when specimens are refrigerated at 4C following collection and while in transit." 9.) Review of "Analytical Validation of SARS-CoV-2 (COVID-19) RT -PCR Assay Using Extraction Free Method", signed by Laboratory director on 11/12/2021, a temperate range for room temperature was not listed in the stability study for testing for COVID-19 specimens, nor for specimens stored in sterile normal saline collection, and the study did not contain positive and negative specimens to validate room temperature. 10.) Review of CFX-96 instrument specimen plate runs on 12/15/2021 and 8/8/2022 revealed Pt#1 to PT#10 were tested for Covid-19 PCR. 11.) During an interview on 10/04/2022 at 3:50 PM, SP#1 (laboratory manager) confirmed the issues of covid-19 specimen storage at room temperature and unvalidated procedure for extraction-less covid-19 method using reagents and controls from Precision Mircobio and Molecular Designs. 12.) The annual COVID-19 testing volume is 100,000.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to determine control procedures based on verified performance specifications for research only positive and negative controls used for one of one (SARS- CoV-2 (COVID-19) RT PCR) test prior to testing patients on 12/15/2021 and for ten of ten patients (PT#1-PT#10) reviewed. Findings included: 1.) During a tour of room "Lab A" on 10/4/2022 at 9:04 AM, revealed a freezer in use for COVID-19. The freezer contained the following open reagents in use: a.) Positive Control Lot#: FG000161. The box states for "Research Use Only. Not for use in diagnostic procedures". b.) Negative Control

	Lot#:NC051022 The box states for "Research Use Only. Not for use in Diagnostic procedures". c.) The reagents had no company name listed on the boxes 2.) Review of "Analytical Validation of SARS-CoV-2 (COVID-19) RT -PCR Assay Using Extraction Free Method", signed by Laboratory director on 11/12/2021, revealed no method for how often controls would be performed or what the quantification cycle (CQ) ranges are to determine a positive and negative result with controls. 3) Review of control and reagent packaging slips revealed the following: a.) controls were sent from Precision Mircobio on 5/18/2022, 5/24/2022 and 1/25/2022. b.) controls were sent from Molecular Designs on 8/24/2022. c.) controls were sent from an unlisted company name on 6/7/2022, 6/21/2022 and 6/28/2022. 4) Review of CFX-96 instrument specimen plate runs on 12/15/2021 and 8/8/2022 revealed Pt#1 to PT#10 were tested Covid-19 PCR. 5) During an interview on 10/4/2022 at 3:50 PM, SP#1 (laboratory manager) confirmed the unvalidated research only positive and negative controls for analytical method of SARS- CoV-2(COVID-19) RT PCR using controls from Molecular Designs and Precision Mircobio. 5) The annual COVID-19 testing volume is 100,000.
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 record review and interview, the laboratory failed to ensure one of eight (SP#2) high complexity testing personnel reviewed, met the qualifications as a high complexity testing person in one of one subspecialty, Virology (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, the laboratory failed to ensure one of eight (SP#2) high complexity testing personnel reviewed, met the qualifications as a high complexity testing person in one of one subspecialty, Virology. Findings include: 1.) During a tour of room "Lab B" on 10/4/2022 at 9:20 AM, SP#2 was performing Covid-19 specimen processing. SP#2 also confirmed the step-by-step method of Covid-19 testing. 2.) Review of CMS-209 LABORATORY PERSONNEL REPORT (CLIA), signed by the laboratory director on 10/3/2022, indicates SP-2 is a testing person. 3.) Review of education and training documentation indicates SP#2 does not qualify as a high complexity testing person. SP#2 has a foreign master's degree from Tribhuvan University in Environmental Science (2019). There was no foreign equivalence to validate the degree for US (United States) education standards or transcripts to validate credits completed. 4.) During an interview on 10/19/2022 at 12: 00 PM, SP#1 (laboratory manager) confirmed SP#2 was not qualified to be testing person and stated that she would be removed from testing.