Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 32D1065537	**(X3) Date Survey Completed** 08/24/2018
Name of Provider or Supplier Lovelace Regional Hospital - Roswell	**Street Address, City, State** 117 East 19th St, Roswell, NM	
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	The following deficiencies were cited during a recertification survey completed on 08/24/2018 for the federal requirements of 42 CFR Part 493 for Laboratories.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of quality control records, laboratory policies manufacturer's instructions, and interviews with laboratory staff, the laboratory failed to perform an external positive and negative control each day of patient testing for the ROM Plus test kit. 446 patients, ROM1 - ROM466 were tested 10/10/2016 - 05/22/2018. Findings are: A. Review of laboratory quality control policy and the manufacturer's instructions revealed the following: 1. The laboratory had updated the (IQCP) Individual Quality Control Plan on 05/22/2018, replacing the name of the previous kit (Amnisure) used for testing vaginal fluid for the presence of amniotic fluid in pregnant women with the new kit, ROM Plus. 2. The laboratory's ROM Plus quality control policy revised on 10/04/2017 indicated the performance of an external positive and a negative control for each new lot or shipment of test kits. Internal or procedural controls were documented with each patient tested. 3. Review of the manufacturer's quality control instructions from the manufacturer's website dated 04/21/2014 indicated that the external quality controls should be performed "every 30 days, or for every new lot number or shipment received, whichever comes first." B. During interview on 08/21/2018 on 08:30 am, the laboratory manager stated that the ROM

Plus kit was already in use by the laboratory when she began working for the laboratory in October 2017. 1. The laboratory manager was unable to locate a copy of the IQCP and correlating studies in use prior to 05/22/2018 for the ROM Plus kit. 2. Review of records for another test system revealed the laboratory had performed a correlation study between the current test kit and the previous kit on an unknown date. However, there were no records indicating the laboratory had completed the study and the new test system was approved by the laboratory director. C. Review of the patient test and quality control records revealed the laboratory started using the new test kit on 10/04/2016. The laboratory failed to perform an external positive and negative control on the following patient test days: October 2016 The external controls were performed on 10/04/2016, 10/10/2016 and 10/28/2016. 10/10/2016 - 2 patients, ROM1 and ROM2 10/11/2016 - 4 patients, ROM3 - ROM6 10/12/2016 - 1 patient, ROM7 10/14/2016 - 1 patient, ROM8 10/17/2016 - 1 patient, ROM9 10/19/2016 - 2 patients, ROM10 and ROM11 10/23/2016 - 1 patient, ROM12 10/25/2016 - 2 patients, ROM13 and ROM14 10/26/2016 - 1 patient, ROM15 10/27/2016 - 1 patient, ROM16 10/28/2016 - 1 patient, ROM17 10/28/2016 - 2 patients ROM18 and ROM19 10/30/2016 - 1 patient, ROM20 10/31/2016 - 1 patient ROM21 November 2016 There was no documentation of external controls in November 2016. 11/02/2016 - 1 patient, ROM22 11/03/2016 - 2 patients, ROM23 and ROM24 11/06/2016 - 1 patient, ROM25 11/08/2016 - 1 patient, ROM26 11/11/2016 - 1 patient, ROM27 11/12/2016 - 1 patient, ROM28 11/13/2016 - 2 patients, ROM29 and ROM30 11/14/2016 - 3 patients, ROM31 - ROM33 11/15/2016 - 1 patient, ROM34 11/16/2016 - 1 patient, ROM35 11/17/2016 - 1 patient, ROM36 11/19/2016 - 1 patient, ROM37 11/20/2016 - 2 patients, ROM38 and ROM39 11/21/2016 - 1 patient, ROM40 11/25/2016 - 1 patient, ROM41 December 2016 The external controls were performed on 12/28 /2016. 12/02/2016 - 3 patients, ROM41-ROM44 12/03/2016 - 1 patient, ROM45 12/04 /2016 - 1 patient, ROM46 12/06/2016 - 4 patients, ROM47-ROM50 12/07/2016 - 1 patient, ROM51 12/09/2016 - 1 patient, ROM52 12/11/2016 - 1 patient, ROM53 12/16 /2016 - 1 patient, ROM54 12/20/2016 - 1 patient, ROM55 12/22/2016 - 1 patient, ROM56 12/23/2016 - 1 patient, ROM57 12/26/2016 - 2 patients, ROM58 and ROM59 12/27/2016 - 2 patients, ROM60 and ROM61 12/28/2016 - 3 patients, ROM62-ROM64 12/29/2016 - 2 patients, ROM65 and ROM66 12/31/2016 - 1 patient, ROM67 January 2017 The external controls were performed on 01/12/2017. 01/02/2017 - 2 patients, ROM68 and ROM69 01/03/2017 - 1 patient, ROM70 01/04/2017 - 2 patients, ROM71 and ROM72 01/05/2017 - 1 patient, ROM73 01/06/2017 - 1 patient, ROM74 01/07/2017 - 1 patient, ROM75 01/09/2017 - 2 patients, ROM76 and ROM77 01/10/2017 - 1 patient, ROM78 01/11/2017 - 1 patient, ROM79 01/14/2017 - 1 patient, ROM80 01/16/2017 - 1 patient, ROM81 01/17/2017 - 1 patient, ROM82 01/18 /2017 - 2 patients, ROM83 and ROM84 01/19/2017 - 1 patient, ROM85 01/20/2017 - 2 patients, ROM86 and ROM87 01/21/2017 - 1 patient, ROM88 01/22/2017 - 1 patient, ROM89 01/23/2017 - 2 patients, ROM90 and ROM91 01/26/2017 - 2 patients, ROM92 and ROM93 01/27/2017 - 1 patient, ROM94 01/31/2017 - 4 patients, ROM95-ROM98 February 2017 The external controls were performed on 02 /04/2017. 02/05/2017 - 1 patient, ROM99 02/08/2017 - 4 patients, ROM100-ROM103 02/09/2017 - 1 patient, ROM104 02/10/2017 - 3 patients, ROM105-ROM107 02/13 /2017 - 1 patient, ROM108 02/14/2017 - 1 patient, ROM109 02/20/2017 - 1 patient, ROM110 02/23/2017 - 1 patient, ROM111 02/25/2017 - 1 patient, ROM112 02/28 /2017 - 2 patients, ROM113-ROM114 March 2017 There was no documentation of external controls in March 2017. 03/01/2017 - 4 patients, ROM115-ROM118 03/02 /2017 - 2 patients, ROM119 and ROM120 03/03/2017 - 2 patients, ROM121 and ROM122 03/04/2017 - 1 patient, ROM123 03/06/2017 - 2 patients, ROM124 and ROM125 03/10/2017 - 1 patient, ROM126 03/11/2017 - 1 patient, ROM127 03/12 /2017 - 1 patient, ROM128 03/16/2017 - 1 patient, ROM129 03/17/2017 - 1 patient,

ROM130 03/20/2017 - 1 patient, ROM131 03/22/2017 - 1 patient, ROM132 03/23 /2017 - 1 patient, ROM133 03/24/2017 - 4 patients, ROM134-ROM137 03/26/2017 - 1 patient, ROM138 April 2017 There was no documentation of external controls in April 2017. 04/01/2017 - 2 patients, ROM139 and ROM140 04/02/2017 - 3 patients, ROM141-ROM143 04/04/2017 - 1 patient, ROM144 04/05/2017 - 1 patient, ROM145 04/06/2017 - 2 patients, ROM146 and ROM147 04/09/2017 - 2 patients, ROM148 and ROM149 04/11/2017 - 1 patient, ROM150 04/12/2017 - 1 patient, ROM151 04/14 /2017 - 1 patient, ROM152 04/15/2017 - 1 patient, ROM153 04/16/2017 - 1 patient, ROM154 04/17/2017 - 1 patient, ROM155 04/18/2017 - 1 patient, ROM156 04/19 /2017 - 1 patient, ROM157 04/20/2017 - 1 patient, ROM158 04/21/2017 - 2 patients, ROM159 and ROM160 04/25/2017 - 2 patients, ROM161 and ROM162 04/26/2017 - 1 patient, ROM163 04/30/2017 - 1 patient, ROM164 May 2017 The external controls were performed on 05/28/2017. 05/01/2017 - 1 patient, ROM165 05/02/2017 - 3 patients, ROM166-ROM168 05/05/2017 - 1 patient, ROM169 05/07/2017 - 2 patients, ROM170 and ROM171 05/08/2017 - 1 patient, ROM172 05/10/2017 - 1 patient, ROM173 05/11/2017 - 1 patient, ROM174 05/13/2017 - 2 patients, ROM175 and ROM176 05/19/2017 - 3 patients, ROM177-ROM179 05/20/2017 - 1 patient, ROM180 05/21/2017 - 3 patients, ROM181-ROM183 05/22/2017 - 3 patients, ROM184-ROM186 05/23/2017 - 2 patients, ROM187 and ROM188 05/24/2017 - 2 patients, ROM189 and ROM190 05/25/2017 - 1 patient, ROM191 05/30/2017 - 1 patient, ROM192 05/31/2017 - 1 patient, ROM193 June 2017 The external controls were performed on 06/16/2017, 06/19/2017, and 06/21/2017. 06/01/2017 - 2 patients, ROM194 and ROM195 06/02/2017 - 1 patient, ROM196 06/05/2017 - 1 patient, ROM197 06/08/2017 - 3 patients, ROM198-ROM200 06/09/2017 - 2 patients, ROM201 and ROM202 06/11/2017 - 1 patient, ROM203 06/14/2017 - 2 patients, ROM204 and ROM205 06/17/2017 - 1 patient, ROM206 06/18/2017 - 1 patient, ROM207 06/20/2017 - 1 patient, ROM208 06/22/2017 - 2 patients, ROM209 and ROM210 06/23/2017 - 2 patients, ROM211 and ROM212 06/24/2017 - 1 patient, ROM213 06/26/2017 - 1 patient, ROM214 06/27/2017 - 1 patient, ROM215 06/28 /2017 - 1 patient, ROM216 06/30/2017 - 1 patient, ROM217 July 2017 The external controls were performed on 07/06/2017. 07/01/2017 - 1 patient, ROM218 07/08/2017 - 3 patients, ROM219-ROM221 07/09/2017 - 1 patient, ROM222 07/10/2017 - 1 patient, ROM223 07/11/2017 - 1 patient, ROM224 07/18/2017 - 3 patients, ROM225-ROM227 07/19/2017 - 1 patient, ROM228 07/20/2017 - 1 patient, ROM229 07/21 /2017 - 2 patients, ROM230 and ROM231 07/22/2017 - 1 patient, ROM232 07/23 /2017 - 2 patients, ROM233 and ROM234 07/25/2017 - 3 patients, ROM235 and ROM237 07/26/2017 - 1 patient, ROM238 07/27/2017 - 1 patient, ROM239 07/29 /2017 - 1 patient, ROM240 07/31/2017 - 1 patient, ROM241 August 2017 There was no documentation of external controls in August 2017. 08/01/2017 - 2 patients, ROM242 and ROM243 08/03/2017 - 2 patients, ROM244 and ROM245 08/07/2017 - 1 patient, ROM246 08/08/2017 - 2 patients, ROM247 and ROM248 08/09/2017 - 1 patient, ROM249 08/10/2017 - 1 patient, ROM250 08/11/2017 - 4 patients, ROM251-ROM254 08/12/2017 - 2 patients, ROM255 and ROM256 08/13/2017 - 2 patients, ROM257 and ROM258 08/21/2017 - 1 patient, ROM259 08/25/2017 - 1 patient, ROM260 08/29/2017 - 1 patient, ROM261 08/31/2017 - 1 patient, ROM262 September 2017 The external controls were performed on 09/17/2017. 09/02/2017 - 5 patients, ROM263-ROM267 09/04/2017 - 1 patient, ROM268 09/05/2017 - 2 patients, ROM269 and ROM270 09/06/2017 - 1 patient, ROM271 09/10/2017 - 2 patients, ROM272 and ROM273 09/12/2017 - 1 patient, ROM274 09/13/2017 - 1 patient, ROM275 09/14/2017 - 4 patients, ROM276-ROM279 09/15/2017 - 2 patients, ROM280 and ROM281 09/16/2017 - 2 patients, ROM282 and ROM283 09/17/2017 - 2 patients, ROM284 and ROM285 09/19/2017 - 1 patient, ROM286 09/20/2017 - 3 patients, ROM287 - ROM289 09/21/2017 - 2 patients, ROM290 and ROM291 09/22

/2017 - 2 patients, ROM292 and ROM294 09/23/2017 - 2 patients, ROM293 and ROM295 09/25/2017 - 2 patients, ROM296 and ROM297 09/26/2017 - 1 patient, ROM298 09/27/2017 - 1 patient, ROM299 09/28/2017 - 1 patient, ROM300 09/29 /2017 - 1 patient, ROM301 09/30/2017 - 1 patient, ROM302 October 2017 The external controls were performed on 10/02/2017. 10/01/2017 - 1 patient, ROM303 10 /07/2017 - 1 patient, ROM304 10/08/2017 - 1 patient, ROM305 10/09/2017 - 2 patients, ROM306 and ROM307 10/11/2017 - 2 patients, ROM308 and ROM309 10 /15/2017 - 2 patients, ROM310 and ROM311 10/16/2017 - 2 patients, ROM312 and ROM313 10/19/2017 - 3 patients, ROM314-ROM316 10/20/2017 - 1 patient, ROM317 10/21/2017 - 1 patient, ROM318 10/23/2017 - 1 patient, ROM319 10/24 /2017 - 2 patients, ROM320 and ROM321 10/29/2017 - 1 patient, ROM322 November 2017 The external controls were performed on 11/10/2017. 11/01/2017 - 1 patient, ROM323 11/04/2017 - 2 patients, ROM324 and ROM325 11/06/2017 - 1 patient, ROM326 11/11/2017 - 3 patients, ROM327-ROM329 11/14/2017 - 2 patients, ROM330 and ROM331 11/15/2017 - 1 patient, ROM332 11/17/2017 - 1 patient, ROM333 11/20/2017 - 1 patient, ROM334 11/23/2017 - 1 patient, ROM335 11/28 /2017 - 1 patient, ROM336 11/29/2017 - 3 patients, ROM337-ROM339 11/30/2017 - 1 patient, ROM340 December 2017 The external controls were performed on 12/16 /2017. 12/01/2017 - 2 patients, ROM341 and ROM342 12/04/2017 - 1 patient, ROM343 12/14/2017 - 3 patients, ROM344-ROM346 12/17/2017 - 1 patient, ROM347 12/19/2017 - 2 patients, ROM348 and ROM349 12/20/2017 - 1 patient, ROM350 12/24/2017 - 2 patients, ROM351 and ROM352 12/25/2017 - 1 patient, ROM353 12/26/2017 - 1 patient, ROM354 12/30/2017 - 1 patient, ROM355 12/31 /2017 - 1 patient, ROM356 January 2018 The external controls were performed on 01 /24/2018. 01/02/2018 - 1 patient, ROM357 01/04/2018 - 2 patients, ROM358 and ROM359 01/05/2018 - 2 patients, ROM360 and ROM361 01/07/2018 - 1 patient, ROM362 01/15/2018 - 1 patient, ROM363 01/17/2018 - 1 patient, ROM364 01/18 /2018 - 1 patient, ROM365 01/19/2018 - 1 patient, ROM366 01/23/2018 - 1 patient, ROM367 01/25/2018 - 1 patient, ROM368 01/26/2018 - 1 patient, ROM369 01/27 /2018 - 2 patients, ROM370 and ROM371 01/30/2018 - 2 patients, ROM372 and ROM373 February 2018 The external controls were performed on 02/22/2018. 02/01 /2018 - 1 patient, ROM374 02/03/2018 - 1 patient, ROM375 02/07/2018 - 2 patients, ROM376 and ROM377 02/08/2018 - 1 patient, ROM378 02/09/2018 - 1 patient, ROM379 02/10/2018 - 2 patients, ROM380 and ROM381 02/15/2018 - 1 patient, ROM382 02/17/2018 - 2 patients, ROM383 and ROM384 02/19/2018 - 1 patient, ROM385 02/20/2018 - 3 patients, ROM386-ROM388 02/23/2018 - 1 patient, ROM389 02/25/2018 - 1 patient, ROM390 02/27/2018 - 2 patients, ROM391 and ROM392 March 2018 The external controls were performed on 03/20/2018. 03/03 /2018 - 2 patients, ROM393 and ROM394 03/04/2018 - 1 patient, ROM395 03/05 /2018 - 2 patients, ROM396 and ROM397 03/10/2018 - 2 patients, ROM398 and ROM399 03/11/2018 - 1 patient, ROM400 03/12/2018 - 2 patients, ROM401 and ROM402 03/16/2018 - 1 patient, ROM403 03/17/2018 - 2 patients, ROM404 and ROM405 03/18/2018 - 1 patient, ROM406 03/21/2018 - 2 patients, ROM407-ROM408 03/23/2018 - 1 patient, ROM409 03/25/2018 - 1 patient, ROM410 03/28 /2018 - 4 patients, ROM411-ROM414 03/30/2018 - 1 patient, ROM415 April 2018 The external controls were performed on 0420/2018. 04/04/2018 - 1 patient, ROM416 04/06/2018 - 2 patients, ROM417 and ROM418 04/10/2018 - 2 patients, ROM419 and ROM420 04/11/2018 - 1 patients, ROM421 04/15/2018 - 1 patient, ROM422 04 /16/2018 - 2 patients, ROM423 and ROM424 04/17/2018 - 1 patient, ROM425 04/18 /2018 - 1 patient, ROM426 04/23/2018 - 1 patient, ROM427 04/24/2018 - 1 patient, ROM428 04/29/2018 - 1 patient, ROM429 04/30/2018 - 1 patient, ROM430 May 2018 The external controls were performed on 05/25/2018. 05/02/2018 - 1 patient, ROM431 05/04/2018 - 1 patient, ROM432 05/07/2018 - 1 patient, ROM433 05/10

	/2018 - 1 patient, ROM434 05/11/2018 - 1 patient, ROM435 05/12/2018 - 4 patients, ROM436-ROM439 05/13/2018 - 1 patient, ROM440 05/19/2018 - 2 patients, ROM441 and ROM442 05/20/2018 - 1 patient, ROM443 05/21/2018 - 1 patient, ROM444 05/22/2018 - 2 patients, ROM445 and ROM446