

Wholepower One Step 2019-Novel Coronavirus (2019-nCoV)

Antigen Test Cassette Clinical Study Report

Reagent Name:

Wholepower One Step 2019-Novel Coronavirus (2019-nCoV) Antigen Test Cassette

Product Code:

7200330

Format:

20 tests / box (individual packing in aluminum pouch)

Main Researcher:

Hongwei Wu, Hong Feng

Study Period:

10/13/2020 - 11/02/2020

Reporting Date:

11/03/2020

| | | | |
|--------------|------------|-------------------|------------------------------|
| Prepared by: | Hongwei Wu | Date: Nov 03,2020 | Signature: <i>Hongwei Wu</i> |
| Checked by: | Hong Feng | Date: Nov 03,2020 | Signature: <i>Hong Feng</i> |



1. Synopsis

The clinical study is to evaluate the clinical sensitivity and specificity of Wholepower One Step 2019-Novel Coronavirus (2019-nCoV) Antigen Test Cassette.

2. Background

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

3. Intended Use

Wholepower One Step 2019-Novel Coronavirus (2019-nCoV) Antigen Test Cassette is an in vitro diagnostic test device intended for the rapid detection of 2019-nCoV antigen in nasopharyngeal swab from patients with suspected 2019-nCoV infection, patients with suspected clustering cases, and others who need to diagnose or differentially diagnose 2019-Novel Coronavirus (2019-nCoV).

4. Material

4.1 Investigational Product name and lot number

Wholepower One Step 2019-Novel Coronavirus (2019-nCoV) Antigen Test Cassette
Lot No.: 20201001

4.2 Comparison method:

2019-nCoV RNA (Multiple PCR-Fluorescence Probing), manufactured by Guangdong Huayin Medicine Science Co., Ltd.

4.3 Nasopharyngeal swab samples from infected patients and non-infected patients

5. Methods

5.1 Demands for the Samples

500 clinical nasopharyngeal swabs were collected from patients who were suspected of COVID-19 (within 7 days of onset). All samples were unaltered clinical specimens and confirmed with RT-PCR. Each sample was blindly labeled by a nonparticipant. Separate sets of the blind coded were assigned. Samples were also randomized prior to testing.

5.2 Each sample was run in 1 test and read the result at 15-20 minutes.

5.3 Interpretation of Results

Negative: Only one color line appears on the control region.

Positive: Two bands are appeared in the test line (T) and control line (C).



Handwritten signature

Invalid: No visible line at all, or there is a visible line only in the test region and not in the control region.

6. Acceptance Criteria:

Total Sensitivity: $\geq 90\%$

Total Specificity: $\geq 97\%$

7. Results

| Test Cassette | RT-PCR | | |
|---------------|----------|----------|-------|
| | positive | negative | total |
| Positive | 106 | 3 | 109 |
| Negative | 4 | 387 | 391 |
| Total | 110 | 390 | 500 |

8. Conclusions:

The sensitivity and specificity for Wholepower One Step 2019-Novel Coronavirus (2019-nCoV) Antigen Test Cassette meet the acceptance criteria.

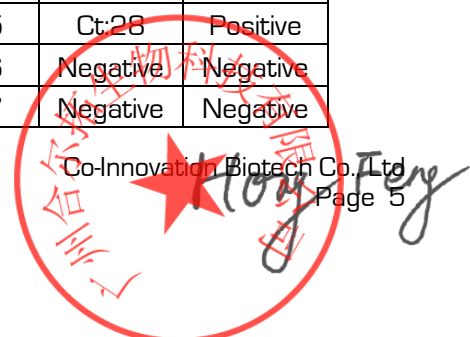
| | Performance | 95%CI |
|-------------|-------------|------------|
| Sensitivity | 96.4% | 91.0-98.6% |
| Specificity | 99.2% | 97.8-99.7% |

9. Raw data

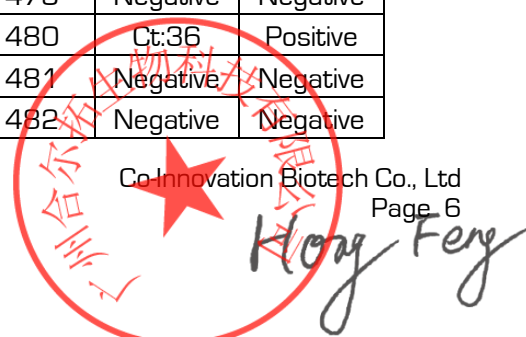
| Evaluated kits: Wholepower One Step 2019-Novel Coronavirus (2019-nCoV) Antigen Test Cassette | | | | | | | | |
|--|----------|---------------|------------|----------|---------------|------------|----------|---------------|
| Lot Number: 20201001 | | | | | | | | |
| Sample No. | RT PCR | Test Cassette | Sample No. | RT PCR | Test Cassette | Sample No. | RT PCR | Test Cassette |
| 1 | Negative | Negative | 168 | Ct:31 | Positive | 335 | Negative | Negative |
| 2 | Negative | Negative | 169 | Negative | Negative | 336 | Negative | Negative |
| 3 | Negative | Negative | 170 | Ct:29 | Positive | 337 | Negative | Negative |
| 4 | Negative | Negative | 171 | Negative | Negative | 338 | Ct:34 | Positive |
| 5 | Ct:23 | Positive | 172 | Ct:33 | Negative | 339 | Negative | Negative |
| 6 | Ct:30 | Positive | 173 | Negative | Negative | 340 | Ct:30 | Positive |
| 7 | Negative | Negative | 174 | Negative | Negative | 341 | Negative | Negative |
| 8 | Negative | Negative | 175 | Negative | Negative | 342 | Ct:35 | Positive |
| 9 | Negative | Negative | 176 | Negative | Negative | 343 | Negative | Negative |
| 10 | Negative | Negative | 177 | Negative | Negative | 344 | Negative | Negative |
| 11 | Negative | Negative | 178 | Negative | Negative | 345 | Negative | Negative |
| 12 | Negative | Negative | 179 | Negative | Negative | 346 | Negative | Negative |
| 13 | Ct:23 | Positive | 180 | Negative | Negative | 347 | Negative | Negative |

| | | | | | | | | |
|----|----------|----------|-----|----------|----------|-----|----------|----------|
| 14 | Ct:32 | Positive | 181 | Ct:33 | Positive | 348 | Negative | Negative |
| 15 | Negative | Negative | 182 | Negative | Negative | 349 | Negative | Negative |
| 16 | Negative | Negative | 183 | Negative | Negative | 350 | Negative | Negative |
| 17 | Negative | Negative | 184 | Negative | Negative | 351 | Ct:32 | Positive |
| 18 | Negative | Negative | 185 | Negative | Negative | 352 | Negative | Negative |
| 19 | Ct:30 | Positive | 186 | Negative | Negative | 353 | Negative | Negative |
| 20 | Negative | Negative | 187 | Negative | Negative | 354 | Negative | Negative |
| 21 | Negative | Negative | 188 | Ct:26 | Positive | 355 | Negative | Negative |
| 22 | Negative | Negative | 189 | Negative | Negative | 356 | Negative | Negative |
| 23 | Negative | Negative | 190 | Negative | Negative | 357 | Negative | Negative |
| 24 | Ct:27 | Positive | 191 | Negative | Negative | 358 | Ct:32 | Positive |
| 25 | Negative | Negative | 192 | Ct:28 | Positive | 359 | Negative | Negative |
| 26 | Negative | Negative | 193 | Ct:32 | Negative | 360 | Negative | Negative |
| 27 | Negative | Negative | 194 | Ct:31 | Positive | 361 | Negative | Negative |
| 28 | Negative | Negative | 195 | Negative | Negative | 362 | Ct:27 | Positive |
| 29 | Negative | Negative | 196 | Negative | Negative | 363 | Negative | Negative |
| 30 | Negative | Negative | 197 | Negative | Negative | 364 | Negative | Negative |
| 31 | Ct:31 | Positive | 198 | Negative | Negative | 365 | Negative | Negative |
| 32 | Negative | Negative | 199 | Negative | Negative | 366 | Ct:27 | Positive |
| 33 | Negative | Negative | 200 | Negative | Negative | 367 | Ct:28 | Positive |
| 34 | Negative | Negative | 201 | Negative | Negative | 368 | Negative | Negative |
| 35 | Negative | Negative | 202 | Negative | Negative | 369 | Ct:29 | Positive |
| 36 | Negative | Negative | 203 | Negative | Negative | 370 | Negative | Negative |
| 37 | Negative | Negative | 204 | Negative | Negative | 371 | Negative | Negative |
| 38 | Ct:31 | Positive | 205 | Negative | Negative | 372 | Negative | Negative |
| 39 | Negative | Negative | 206 | Negative | Negative | 373 | Negative | Negative |
| 40 | Negative | Negative | 207 | Negative | Negative | 374 | Negative | Negative |
| 41 | Negative | Negative | 208 | Negative | Negative | 375 | Negative | Negative |
| 42 | Negative | Negative | 209 | Ct:37 | Positive | 376 | Negative | Negative |
| 43 | Negative | Negative | 210 | Ct:28 | Positive | 377 | Negative | Negative |
| 44 | Negative | Negative | 211 | Negative | Negative | 378 | Ct:29 | Positive |
| 45 | Negative | Negative | 212 | Negative | Negative | 379 | Ct:32 | Positive |
| 46 | Ct:29 | Positive | 213 | Negative | Negative | 380 | Ct:29 | Positive |
| 47 | Negative | Negative | 214 | Negative | Negative | 381 | Negative | Negative |
| 48 | Ct:28 | Positive | 215 | Negative | Negative | 382 | Negative | Negative |
| 49 | Negative | Negative | 216 | Ct:31 | Positive | 383 | Negative | Negative |
| 50 | Negative | Negative | 217 | Negative | Negative | 384 | Negative | Negative |
| 51 | Negative | Negative | 218 | Negative | Negative | 385 | Negative | Negative |
| 52 | Negative | Negative | 219 | Negative | Negative | 386 | Ct:27 | Positive |
| 53 | Ct:31 | Positive | 220 | Negative | Negative | 387 | Negative | Negative |
| 54 | Negative | Negative | 221 | Negative | Negative | 388 | Negative | Negative |
| 55 | Negative | Negative | 222 | Ct:30 | Positive | 389 | Negative | Negative |
| 56 | Negative | Negative | 223 | Negative | Negative | 390 | Negative | Negative |
| 57 | Ct:27 | Positive | 224 | Negative | Negative | 391 | Ct:31 | Positive |
| 58 | Negative | Negative | 225 | Negative | Negative | 392 | Negative | Negative |

| | | | | | | | | |
|-----|----------|----------|-----|----------|----------|-----|----------|----------|
| 59 | Negative | Negative | 226 | Negative | Negative | 393 | Negative | Negative |
| 60 | Negative | Negative | 227 | Negative | Negative | 394 | Negative | Negative |
| 61 | Negative | Negative | 228 | Negative | Negative | 395 | Negative | Negative |
| 62 | Negative | Negative | 229 | Negative | Negative | 396 | Negative | Negative |
| 63 | Negative | Negative | 230 | Negative | Negative | 397 | Negative | Negative |
| 64 | Ct:30 | Positive | 231 | Negative | Negative | 398 | Negative | Negative |
| 65 | Ct:34 | Positive | 232 | Negative | Negative | 399 | Ct:37 | Positive |
| 66 | Negative | Negative | 233 | Negative | Negative | 400 | Negative | Negative |
| 67 | Negative | Negative | 234 | Negative | Negative | 401 | Negative | Negative |
| 68 | Ct:32 | Positive | 235 | Negative | Negative | 402 | Negative | Negative |
| 69 | Negative | Negative | 236 | Negative | Negative | 403 | Negative | Negative |
| 70 | Negative | Negative | 237 | Ct:28 | Positive | 404 | Negative | Negative |
| 71 | Ct:31 | Positive | 238 | Negative | Negative | 405 | Negative | Negative |
| 72 | Negative | Negative | 239 | Negative | Negative | 406 | Ct:27 | Positive |
| 73 | Negative | Negative | 240 | Ct:28 | Positive | 407 | Negative | Negative |
| 74 | Negative | Negative | 241 | Ct:26 | Positive | 408 | Negative | Negative |
| 75 | Negative | Negative | 242 | Negative | Negative | 409 | Negative | Negative |
| 76 | Negative | Negative | 243 | Ct:30 | Positive | 410 | Negative | Negative |
| 77 | Ct:29 | Positive | 244 | Negative | Negative | 411 | Negative | Negative |
| 78 | Ct:26 | Positive | 245 | Negative | Negative | 412 | Negative | Negative |
| 79 | Negative | Negative | 246 | Negative | Negative | 413 | Negative | Negative |
| 80 | Negative | Negative | 247 | Negative | Negative | 414 | Negative | Negative |
| 81 | Negative | Negative | 248 | Negative | Negative | 415 | Ct:30 | Positive |
| 82 | Negative | Negative | 249 | Negative | Negative | 416 | Negative | Negative |
| 83 | Negative | Negative | 250 | Negative | Negative | 417 | Negative | Negative |
| 84 | Negative | Negative | 251 | Negative | Negative | 418 | Negative | Negative |
| 85 | Negative | Negative | 252 | Negative | Negative | 419 | Ct:26 | Positive |
| 86 | Negative | Negative | 253 | Ct:36 | Positive | 420 | Negative | Negative |
| 87 | Negative | Negative | 254 | Negative | Negative | 421 | Negative | Negative |
| 88 | Negative | Negative | 255 | Negative | Negative | 422 | Ct:26 | Positive |
| 89 | Negative | Negative | 256 | Negative | Negative | 423 | Negative | Negative |
| 90 | Ct:35 | Negative | 257 | Ct:31 | Positive | 424 | Negative | Negative |
| 91 | Negative | Negative | 258 | Negative | Negative | 425 | Negative | Negative |
| 92 | Negative | Negative | 259 | Negative | Negative | 426 | Negative | Negative |
| 93 | Negative | Negative | 260 | Ct:28 | Positive | 427 | Negative | Negative |
| 94 | Ct:35 | Positive | 261 | Negative | Negative | 428 | Ct:25 | Positive |
| 95 | Negative | Negative | 262 | Negative | Negative | 429 | Ct:32 | Positive |
| 96 | Negative | Negative | 263 | Negative | Negative | 430 | Negative | Negative |
| 97 | Negative | Negative | 264 | Negative | Negative | 431 | Negative | Negative |
| 98 | Negative | Negative | 265 | Negative | Negative | 432 | Negative | Negative |
| 99 | Negative | Negative | 266 | Ct:34 | Positive | 433 | Negative | Negative |
| 100 | Ct:28 | Positive | 267 | Negative | Negative | 434 | Negative | Negative |
| 101 | Negative | Negative | 268 | Negative | Negative | 435 | Ct:28 | Positive |
| 102 | Ct:33 | Positive | 269 | Ct:29 | Positive | 436 | Negative | Negative |
| 103 | Negative | Negative | 270 | Negative | Negative | 437 | Negative | Negative |



| | | | | | | | | |
|-----|----------|----------|-----|----------|----------|-----|----------|----------|
| 104 | Negative | Negative | 271 | Negative | Negative | 438 | Negative | Negative |
| 105 | Negative | Negative | 272 | Ct:26 | Positive | 439 | Negative | Negative |
| 106 | Negative | Negative | 273 | Negative | Negative | 440 | Ct:29 | Positive |
| 107 | Negative | Negative | 274 | Ct:30 | Positive | 441 | Negative | Negative |
| 108 | Negative | Negative | 275 | Ct:27 | Positive | 442 | Negative | Negative |
| 109 | Ct:31 | Positive | 276 | Negative | Negative | 443 | Ct:31 | Positive |
| 110 | Negative | Negative | 277 | Negative | Negative | 444 | Negative | Negative |
| 111 | Ct:28 | Positive | 278 | Negative | Negative | 445 | Ct:31 | Negative |
| 112 | Negative | Negative | 279 | Negative | Negative | 446 | Negative | Negative |
| 113 | Negative | Negative | 280 | Negative | Negative | 447 | Negative | Negative |
| 114 | Negative | Negative | 281 | Negative | Negative | 448 | Ct:24 | Positive |
| 115 | Negative | Negative | 282 | Negative | Negative | 449 | Negative | Positive |
| 116 | Ct:29 | Positive | 283 | Negative | Negative | 450 | Negative | Negative |
| 117 | Negative | Negative | 284 | Negative | Negative | 451 | Ct:24 | Positive |
| 118 | Ct:30 | Positive | 285 | Negative | Negative | 452 | Negative | Negative |
| 119 | Negative | Negative | 286 | Ct:27 | Positive | 453 | Negative | Negative |
| 120 | Negative | Negative | 287 | Ct:32 | Positive | 454 | Negative | Negative |
| 121 | Negative | Negative | 288 | Negative | Negative | 455 | Negative | Negative |
| 122 | Negative | Negative | 289 | Negative | Negative | 456 | Negative | Negative |
| 123 | Negative | Negative | 290 | Negative | Negative | 457 | Ct:33 | Positive |
| 124 | Negative | Negative | 291 | Negative | Negative | 458 | Negative | Negative |
| 125 | Ct:30 | Positive | 292 | Negative | Negative | 459 | Negative | Negative |
| 126 | Negative | Negative | 293 | Negative | Negative | 460 | Negative | Negative |
| 127 | Negative | Negative | 294 | Negative | Negative | 461 | Negative | Negative |
| 128 | Negative | Negative | 295 | Negative | Negative | 462 | Ct:29 | Positive |
| 129 | Negative | Negative | 296 | Negative | Negative | 463 | Negative | Negative |
| 130 | Negative | Negative | 297 | Negative | Negative | 464 | Negative | Negative |
| 131 | Negative | Negative | 298 | Negative | Negative | 465 | Negative | Negative |
| 132 | Negative | Negative | 299 | Negative | Negative | 466 | Ct:28 | Positive |
| 133 | Ct:29 | Positive | 300 | Negative | Negative | 467 | Negative | Negative |
| 134 | Ct:24 | Positive | 301 | Negative | Negative | 468 | Negative | Negative |
| 135 | Negative | Negative | 302 | Negative | Negative | 469 | Negative | Negative |
| 136 | Negative | Negative | 303 | Ct:32 | Positive | 470 | Ct:28 | Positive |
| 137 | Negative | Negative | 304 | Negative | Negative | 471 | Negative | Negative |
| 138 | Negative | Negative | 305 | Negative | Negative | 472 | Negative | Negative |
| 139 | Ct:29 | Positive | 306 | Negative | Negative | 473 | Negative | Negative |
| 140 | Ct:32 | Positive | 307 | Negative | Negative | 474 | Negative | Negative |
| 141 | Negative | Negative | 308 | Negative | Negative | 475 | Ct:29 | Positive |
| 142 | Negative | Negative | 309 | Negative | Negative | 476 | Ct:32 | Positive |
| 143 | Negative | Negative | 310 | Negative | Negative | 477 | Negative | Negative |
| 144 | Negative | Negative | 311 | Negative | Negative | 478 | Negative | Negative |
| 145 | Negative | Negative | 312 | Negative | Negative | 479 | Negative | Negative |
| 146 | Ct:30 | Positive | 313 | Negative | Negative | 480 | Ct:36 | Positive |
| 147 | Negative | Negative | 314 | Negative | Negative | 481 | Negative | Negative |
| 148 | Negative | Negative | 315 | Ct:35 | Positive | 482 | Negative | Negative |



| | | | | | | | | |
|-----|----------|----------|-----|----------|----------|-----|----------|----------|
| 149 | Negative | Negative | 316 | Negative | Negative | 483 | Negative | Negative |
| 150 | Ct:28 | Positive | 317 | Negative | Negative | 484 | Negative | Negative |
| 151 | Ct:33 | Positive | 318 | Ct:30 | Positive | 485 | Negative | Negative |
| 152 | Ct:26 | Positive | 319 | Ct:30 | Positive | 486 | Negative | Negative |
| 153 | Negative | Negative | 320 | Negative | Positive | 487 | Ct:26 | Positive |
| 154 | Negative | Negative | 321 | Negative | Negative | 488 | Negative | Negative |
| 155 | Ct:33 | Positive | 322 | Negative | Negative | 489 | Ct:31 | Positive |
| 156 | Negative | Negative | 323 | Ct:27 | Positive | 490 | Negative | Negative |
| 157 | Negative | Positive | 324 | Negative | Negative | 491 | Negative | Negative |
| 158 | Ct:28 | Positive | 325 | Negative | Negative | 492 | Negative | Negative |
| 159 | Negative | Negative | 326 | Negative | Negative | 493 | Ct:29 | Positive |
| 160 | Negative | Negative | 327 | Ct:28 | Positive | 494 | Negative | Negative |
| 161 | Negative | Negative | 328 | Negative | Negative | 495 | Negative | Negative |
| 162 | Ct:32 | Positive | 329 | Negative | Negative | 496 | Negative | Negative |
| 163 | Negative | Negative | 330 | Negative | Negative | 497 | Negative | Negative |
| 164 | Negative | Negative | 331 | Negative | Negative | 498 | Negative | Negative |
| 165 | Ct:25 | Positive | 332 | Negative | Negative | 499 | Ct:23 | Positive |
| 166 | Negative | Negative | 333 | Ct:32 | Positive | 500 | Negative | Negative |
| 167 | Negative | Negative | 334 | Negative | Negative | | | |

Ct: Cycle threshold

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