

1 **Clinical Evaluation of Three Sample-To-Answer Platforms for the Detection of SARS-CoV-2**

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3 Running title: Three Sample-To-Answer Platforms for SARS-CoV-2 Detection

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5 Wei Zhen<sup>1\*</sup>, Elizabeth Smith<sup>1\*</sup> Ryhana Manji<sup>1</sup>, Deborah Schron<sup>2</sup>, Gregory J. Berry<sup>1,2</sup>

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7 1. Infectious Disease Diagnostics, Northwell Health Laboratories, Lake Success, NY

8 2. Department of Pathology and Laboratory Medicine, The Donald and Barbara Zucker School of  
9 Medicine at Hofstra/Northwell

10 \*These authors contributed equally to this work. Author name order was determined by a coin toss.

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12 Corresponding author:

13 Gregory J. Berry, Ph.D., D(ABMM), Infectious Disease Diagnostics, Northwell Health Laboratories, 450

14 Lakeville Rd., Lake Success, NY 11042

15

16 Phone: 516.224.8506, FAX: 718.224.6585; email: gberry1@northwell.edu

17 **Abstract**

18 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has now spread across the  
19 globe. As part of the worldwide response, many molecular diagnostic platforms have been granted  
20 Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA) to identify SARS-CoV-2  
21 positive patients. Our objective was to evaluate three sample-to-answer molecular diagnostic platforms  
22 (Cepheid Xpert® Xpress SARS-CoV-2 [Xpert Xpress], Abbott ID NOW™ COVID-19 [ID NOW], GenMark  
23 ePlex® SARS-CoV-2 Test [ePlex]) to determine analytical sensitivity, clinical performance, and workflow  
24 for the detection of SARS-CoV-2 in nasopharyngeal swabs from 108 symptomatic patients. We found  
25 that the Xpert Xpress had the lowest limit of detection (100% detection at 100 copies/mL), followed by  
26 the ePlex (100% detection at 1,000 copies/mL), and the ID NOW (20,000 copies/mL). The Xpert Xpress  
27 also had highest positive percent agreement (PPA) when compared to our reference standard (98.3%)  
28 followed by the ePlex (91.4%) and ID now (87.7%). All three assays showed 100% negative percent  
29 agreement (NPA). In the workflow analysis, the ID NOW produced the most rapid time to result per  
30 specimen (~17 minutes) as compared to the Xpert Xpress (~46 minutes) and the ePlex (~1.5 hours), but  
31 what the ID NOW gained in rapid results, it lost in analytical and clinical performance. The ePlex had the  
32 longest time to results and showed a slight improvement in PPA over the ID NOW. Information about  
33 the clinical and analytical performance of these assays, as well as workflow, will be critical in making  
34 informed and timely decisions on testing platform.

35

36 **Keywords:** SARS-CoV-2, COVID-19, EUA, molecular diagnostics, near patient testing, nasopharyngeal

37 **Introduction:**

38 The outbreak of SARS-CoV-2 and subsequent cases of COVID-19 (1), which began in Wuhan,  
39 China by the end of December 2019, has spread to more than 200 countries and territories. As of April  
40 15, 2020, over two million cases have been confirmed, causing over ~133,000 deaths according to the  
41 Centers for Disease Control and Prevention (CDC) and database from the Center for System Science and  
42 Engineering (CSSE) at Johns Hopkins University (2, 3).

43 SARS-CoV-2 is the seventh coronavirus known to be transmitted from human to human, has  
44 high rates of transmission, and is also relatively stable in aerosols and on surfaces (4, 5, 6). Infection with  
45 SARS-CoV-2 can cause mild to severe respiratory illness, including symptoms such as fatigue, shortness  
46 of breath, cough, and fever. In addition, some individuals experience rapidly progressive and severe  
47 disease. The elderly and those with serious underlying medical conditions (e.g. cardiovascular disease,  
48 diabetes, lung disease, and immunocompromised individuals) are most at risk of developing fulminant  
49 disease (4). Currently, there are no available specific therapeutics, or vaccines approved by the FDA for  
50 treatment or prevention of COVID-19 (7). In addition, the SARS-CoV-2 pandemic has coincided with  
51 influenza season in many locations. These challenges have presented a major hurdle for slowing the  
52 global spread of disease and have necessitated the need for rapid and accurate SARS-CoV-2 diagnostic  
53 testing to implement effective infection control measures.

54 Currently available molecular diagnostics platforms include several sample-to-answer platforms that  
55 have been issued an EUA by the FDA to qualitatively detect SARS-CoV-2 RNA in symptomatic patients.  
56 All three sample-to-answer platforms evaluated in this study are individual cartridge-based tests are  
57 likely to be widely utilized by hospital laboratories. In addition, both the Xpert Xpress and the ID NOW  
58 are also authorized to be used in patient care settings outside of the clinical laboratory environment and  
59 are therefore highly likely to be considered for patient testing in the outpatient environment.

60 In this study, our objective was to evaluate the analytical and clinical performance, as well as the  
61 workflow of these three sample-to-answer platforms for SARS-CoV-2 detection in 108 nasopharyngeal  
62 swab specimens from symptomatic patients.

63 **Materials and Methods**

64 **Specimen collection and storage.** Nasopharyngeal (NP) swabs were collected from symptomatic  
65 patients. A sterile swab made from Dacron, rayon or nylon was used for each collection. The NP swab  
66 was then placed into sterile 3 mL universal transport medium (UTM- various manufacturers). Samples  
67 were then transported and tested as close to collection time as possible. Storage of specimens occurred  
68 at 2-8°C for up to 72 hours. Following routine patient testing, samples were aliquoted and stored at -  
69 80°C until comparator testing could occur.

70

71 **Study design.**

72 A total of 108 nasopharyngeal samples (50 negative and 58 positive specimens) tested between March  
73 to April of 2020 were selected for this study and included symptomatic patients of all genders and ages.  
74 This work was conducted as a quality improvement activity in order to complete each assay validation.  
75 The 108 specimens included 88 retrospective samples initially tested on the ePlex and then immediately  
76 aliquoted and frozen at -80°C, remaining frozen until this study was performed. Retrospective samples  
77 were thawed and immediately tested on the Hologic Panther Fusion® SARS-CoV-2 assay (Reference  
78 standard), ID NOW and Xpert Xpress assays. The prospective 20 specimens were performed fresh on  
79 each platform at the time of patient testing. The specimens selected represented our true positivity rate  
80 at the time this study was performed (50 - 60%) and also included positive specimens spanning the  
81 range of positivity, including those with low viral loads (characterized by high cycle threshold (Ct) values  
82 obtained by the reference method).

83

84 **Cepheid Xpert® Xpress SARS-CoV-2 assay.** The Xpert Xpress assay is a molecular *in vitro* diagnostic test  
85 utilizing widely-used real time RT-PCR amplification technology to detect the nucleocapsid gene (N2)  
86 and the envelope gene (E) in upper respiratory specimens and is performed on GeneXpert instrument

87 system. All testing was performed according to the manufacturer's instructions. Briefly, the specimen  
88 collection tube is mixed by rapidly inverting five times and then 300  $\mu$ L of NP specimen is transferred to  
89 the sample chamber of the assay cartridge. The lid is then closed and the cartridge is loaded onto the  
90 GeneXpert platform, which performs automated sample processing, and real time RT-PCR for viral RNA  
91 detection.

92

93 **Abbott ID NOW™ COVID-19 assay.** The ID NOW is a rapid molecular *in vitro* diagnostic test utilizing  
94 isothermal nucleic acid amplification technology to detect the RNA-dependent RNA polymerase (RdRp)  
95 gene segment of the SARS-CoV-2 virus and is performed on the ID Now instrument. It consists of a  
96 Sample Receiver containing elution/lysis buffer, a Test Base, and a Transfer Cartridge for transfer of the  
97 eluted sample to the Test Base, and ID NOW instrument. All testing was performed according to the  
98 manufacturer's instructions. Briefly, a Test Base and a Sample Receiver are inserted into the ID now  
99 instrument. When instructed via on-screen instructions, 200  $\mu$ L of NP specimen is added to the Sample  
100 Receiver and then immediately transferred to the Test Base using the provided Transfer Cartridge,  
101 initiating target amplification.

102

103 **GenMark ePlex® SARS-CoV-2 assay.** The ePlex assay is an *in vitro* diagnostic test that targets the N gene  
104 of SARS-CoV-2 and uses combined electrowetting and GenMark's eSensor® technology for the  
105 extraction, amplification and detection using competitive DNA hybridization and electrochemical  
106 detection. All testing was performed according to the manufacturer's instructions. Briefly, the specimen  
107 is initially vortexed and 200  $\mu$ L of NP specimen is added to the sample delivery device (SDD) provided  
108 with the ePlex SARS-CoV-2 kit and vortexed for 10 seconds. The entire volume of the SDD is dispensed  
109 into the sample loading port of SARS-CoV-2 test cartridge, followed by pushing down the cap to seal the  
110 sample delivery port. The cartridge is bar-coded and scanned with the ePlex® instrument barcode

111 scanner, then is loaded into an available ePlex bay, which performs extraction, amplification, and  
112 detection.

113

114 **Hologic Panther Fusion® SARS-CoV-2 assay (Reference Standard assay).** The Fusion SARS-CoV-2 assay  
115 was used as the reference standard for all three assays evaluated in this study and was performed  
116 according to the manufacturer's instructions for use. NP specimens are lysed by transferring 500 µL of  
117 specimen into a Specimen Lysis Tube containing 710 µL lysis buffer and loaded onto the instrument. An  
118 Internal Control is added to each specimen by the working Panther Fusion Capture Reagent-S and  
119 hybridized nucleic acid is then separated using a magnetic field. Following wash steps, 50 µL of purified  
120 RNA is eluted. Then 5 µL of eluted nucleic acid is transferred to a Panther Fusion reaction tube. The  
121 Fusion® SARS-CoV-2 assay amplifies and detects two conserved regions of the ORF1ab gene in the same  
122 fluorescence channel, with amplification of either or both regions leading to a fluorescent ROX signal.  
123 Reporting of a positive specimen requires only one of the two targets to be detected (ORF1a or ORF1b  
124 gene).

125

126 **Analytical Sensitivity.** Limit of detection (LoD) was performed using the Exact Diagnostics synthetic RNA  
127 quantified control (SARS-CoV-2 Standard) containing five gene targets (E, N, ORF1ab, RdRP and S Genes  
128 of SARS-CoV-2 (SKU COV019, Fort Worth, TX). A starting concentration of 200,000 copies/mL control  
129 was used to prepare a serial dilution panel. The control material was prepared using Ambion® RNA  
130 Storage Solution (Catalog No. AM7001, ThermoFisher Scientific) to limit the potential of degradation of  
131 the RNA transcript and aliquoted for testing to obtain replicates at 20,000, 10,000, 5,000, 2,000, 1,000,  
132 500, 100, 50, and 5 copies/mL (with replicates ranging from 1-10, as shown in **Table 1**). Positive rate was  
133 defined as the lowest dilution at which all replicates were positive at a 100% detection rate and was  
134 used to evaluate the analytical sensitivity of all three sample-to-answer platforms.

135 **Statistical methods.** The reference standard was established as the result obtained from the Hologic  
136 Panther Fusion® SARS-CoV-2 assay. Percent positive agreement (PPA), percent negative agreement  
137 (NPA), positivity rate, Kappa, and two-sided (upper/lower) 95% confidence interval (CI) were calculated  
138 using Microsoft® Office Excel 365 MSO software (Microsoft, Redmond, WA). Cohen's kappa values ( $\kappa$ )  
139 were calculated as a measure of overall agreement, with values categorized as almost-perfect ( $>0.90$ ),  
140 strong (0.80 to 0.90), moderate (0.60 to 0.79), weak (0.40 to 0.59), minimal (0.21 to 0.39), or none (0 to  
141 0.20) (8-9). The dose-response 95th percentile (with 95% confidence interval [CI]) model was assessed  
142 using the Finney and Stevens calculations (10).



143 **Results**

144 **Analytical Sensitivity.**

145 LoD was determined by preparing serial dilutions ranging from 20,000 to 5 copies/mL using a known  
146 concentration of the Exact Diagnostics SARS-CoV-2 control panel and was defined as the minimum  
147 concentration with detection of 100% by positive rate. The LoD established by percent positive rate and  
148 the manufacturer's interpretation algorithm for each assay was determined to be 20,000 copies/mL for  
149 the ID NOW, 1,000 copies/mL for the ePlex, and 100 copies/mL by the Xpert Xpress assay (including  
150 presumptive positive results) (**Table 1**).

151 **Clinical performance**

152 Clinical testing was performed on 108 retrospective and prospective clinical specimens, and was  
153 compared to the reference standard. The Xpert Xpress demonstrated a PPA of 98.3%, followed by the  
154 ePlex at 91.4% and the ID NOW at 87.9%. NPA was also calculated and was 100% for each platform  
155 evaluated (**Table 2**). One sample was invalid on the ID NOW and was not included in the calculations for  
156 this platform. When distribution of positive results was further evaluated across all three platforms, the  
157 Xpert Xpress detected a total of 57 positive results, followed by the ePlex at 53 and the ID NOW at 50.  
158 The ePlex also detected 3 positive results that were not detected by the ID NOW and the ID NOW  
159 detected 1 positive result that was not detected by the ePlex, but all 4 of these positive results were  
160 detected by the Xpert Xpress, as well as 4 additional positive results that were only detected by the  
161 Xpert Xpress. The ePlex and the ID NOW did not detect any additional results that were not detected by  
162 the Xpert Xpress. One specimen that was positive on Panther fusion was not detected on all 3 platforms.  
163 A total of eight discordant samples were found among the three sample-to-answer platforms evaluated,  
164 with ID NOW having the most discordant results (n=7), followed by the ePlex (n=5), and the Xpert Xpress  
165 (n=1). All discordant results were negative results as compared to a positive result from the reference  
166 method. When evaluating cycle threshold (Ct) values obtained from the reference method, A-24, which

167 was the only discordant specimen by the Xpert Xpress assay, had a Ct value of 38.5, which would be  
168 considered a low viral load positive specimen. The ePlex exhibited negative results with specimens that  
169 had Ct values ranging from 33.1- 38.5, while the ID now ranged 32- 38.5 (**Table 3**).

170 Hands on time (HoT), run time, and total turnaround time (TAT) per specimen were evaluated.  
171 The Xpert Xpress HoT is approximately one minute per specimen, while the ID NOW and the ePlex both  
172 had a HoT of approximately two minutes per specimen. The ID NOW had the shortest overall TAT of ~17  
173 minutes for one specimen. Xpert Xpress TAT was ~ 46 minutes and ePlex TAT was ~1.5 hours for one  
174 specimen, with the majority of TAT on each assay being assay run time. The ID NOW turnaround time  
175 can also differ for positive specimens, which can be as low as 5 minutes, including HoT (**Table 4**).

176 **Discussion**

177 Clinical confirmation of COVID-19 is at the core of our strategy to stop the current spread of  
178 infection. It has recently been shown that SARS-CoV-2 has a basic reproduction number ( $R_0$ ) of 2.2,  
179 meaning that an infected person, on average, can spread the infection to two additional persons (5, 6).

180 Vulnerable patient populations are especially at risk, such as people with pre-existing medical  
181 conditions, immunocompromised individuals, and the elderly, especially people living in a nursing home  
182 or long-term care facility (11, 12). With this in mind, it is critical that patient results are as accurate as  
183 possible and are also available in a rapid fashion to stop the spread of infection in real-time.

184 We evaluated three sample-to-answer platforms currently in use in our health system for the  
185 detection of SARS-CoV-2, including the Xpert Xpress and ID Now, which are designed to be performed in  
186 near patient testing environments and outside of the clinical laboratory environment. LoD  
187 determination, correlation of clinical results, and performance comparisons, including HoT and overall  
188 TAT for each assay were done as part of our evaluation. This information is especially critical at the  
189 current moment, where accurate and rapid results are at the center of clinical decision-making, both in  
190 the outpatient clinics and in the hospital. All three of these platforms are designed to produce rapid test  
191 results and each platform is a sample-to-answer system designed to run one patient per test cartridge.  
192 This makes the comparison of these platforms especially pertinent as decisions are made for testing in  
193 both the inpatient and outpatient environments.

194 When we compared all three platforms, the Xpert Xpress out-performed both the ID NOW and  
195 the ePlex, exhibiting the lowest LoD of all three platforms at 100 copies/mL, whereas the ID NOW and  
196 ePlex had higher LoDs of 20,000 and 1,000 copies/mL, respectively (**Table 1**). We also observed that in  
197 each case, the manufacturer's stated LoD differed from our findings, with the ePlex having a much lower  
198 LoD than that stated in their EUA submission (1,000 RNA copies/mL vs. EUA-listed 100,000 RNA  
199 transcript copies/mL), while the ID NOW had a much higher LoD than what was stated in their EUA

200 submission (20,000 RNA transcript copies/mL vs. EUA-listed 125 genome equivalents/mL). Xpert Xpress  
201 had the closest manufacturer's stated LoD (100 RNA transcript copies/mL, including presumptive  
202 positives vs. EUA-stated 250 copies /mL). This may be due to different quantified materials being used  
203 by each manufacturer. Our LoD findings also correlated with the clinical sensitivities, which ranged from  
204 a high of 98.3% for the Xpert Xpress to a low of 87.9% for the ID Now, with the ePlex falling in the  
205 middle at 91.4% (**Table 2**). A closer analysis of positive results showed that while the majority of  
206 positives were detected by all three platforms, the Xpert Xpress also detected four results that were  
207 missed by both the ID NOW and the ePlex, and also detected additional results singly detected by either  
208 the ID NOW, or the ePlex. All three assays had 100% specificity and did not exhibit false positive results.

209         When it comes to the HoT and TAT of the three platforms, each platform has specific  
210 advantages. The Xpert Xpress is the easiest to use with the least technical interventions, which include  
211 loading the sample and the cartridge. The ID NOW has the shortest sample to answer time at ~17  
212 minutes maximum to final result. The ePlex has the ability to tests more patients at once on a random  
213 access 6 bay tower. Both the Xpert Xpress and ePlex platforms can also be expanded by adding  
214 modules/bays for more capacity in certain models of instrumentation, while the ID NOW is limited to 1  
215 sample testing port per instrument.

216         Some limitations of this study are that this is a single-center study and the majority of specimens  
217 were initially tested on the ePlex system and were then stored frozen. While this is the case, the ePlex  
218 had sensitivity performance considerably lower than that of the reference standard (Panther Fusion)  
219 and the Xpert Xpress, yet had the competitive advantage as the assay that was initially performed on  
220 fresh specimens. Considering this workflow limitation, the results of our study in regards to the  
221 sensitivity of the ePlex are even more telling, since the ePlex results do not contain testing after one  
222 freeze-thaw of retrospective specimens, such as was the case for the Xpert Xpress and the ID NOW (as  
223 well as the Reference standard).

224 In addition, while the number of specimens included in the clinical correlation was only 108,  
225 these specimens were chosen to span the positivity range of clinical specimens, including those  
226 specimens with a low viral load. Also, the percentage of positive specimens in our study actually  
227 reflected our overall true positivity rate (50-60% SARS-CoV-2 positive) for this time period.

228 In summary, we evaluated three sample-to-answer platforms for the detection of SARS-CoV-2  
229 using NP specimens, including two platforms that are designed to be done in the near patient testing  
230 environment, the Xpert Xpress and the ID NOW. Our results showed that the Xpert Xpress performed  
231 well and had the lowest LoD and highest sensitivity, while the ePlex and ID NOW had lower sensitivities  
232 and missed several positive patient specimens. The lack of sensitivity in both the ID NOW and ePlex is  
233 particularly concerning in the midst of this current pandemic, where identifying new infections is the  
234 bedrock of limiting spread. While the ID NOW is the most rapid of the three platforms tested, taking ~17  
235 minutes to complete from beginning to end, it missed 12.3% of positive patients tested, exhibiting a  
236 sensitivity of 87.7% in our study. The ePlex also missed 8.6% of positive patients and had a sensitivity of  
237 91.4%, and also takes ~1.5 hours to perform. In contrast, the Xpert Xpress missed 1.7% of positive  
238 patients, showing a sensitivity of 98.3% and takes ~46 minutes to perform. In conclusion, while the ID  
239 NOW gives the most rapid result, both the ID NOW and the ePlex (which takes substantially longer to  
240 result) lack sensitivity as compared to the Xpert Xpress. These parameters will need to be considered  
241 when deciding which testing platform should be implemented for COVID-19 testing.

242 **Acknowledgements and Disclosures**

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283



284 **Table 1.** Summary of Limit of Detection results.

Molecular Assay	Positive Rate % <sup>a</sup>										Final LoD <sup>b</sup> copies/mL
	20,000	10,000	5,000	2,000	1,000	500	100	50	5		
Xpert Xpress	N2	1/1 (100%)	N/A	N/A	10/10 (100%)	<b>9/9</b> (100%)	9/10 (90%)	7/10 (70%)	4/8 (50%)	0/5 (0%)	<b>100<sup>c</sup></b>
	E	1/1 (100%)	N/A	N/A	10/10 (100%)	9/9 (100%)	10/10 (100%)	<b>10/10</b> (100%)	7/8 (87.5%)	0/5 (0%)	
ID NOW	RdRp	<b>5/5</b> (100%)	8/10 (80%)	5/10 (50%)	5/10 (50%)	0/8 (0%)	0/1 (0%)	0/1 (0%)	0/1 (0%)	0/1 (0%)	<b>20,000</b>
ePlex	N	10/10 (100%)	N/A	N/A	10/10 (100%)	<b>9/9</b> (100%)	7/10 (70%)	1/10 (10%)	1/4 (25%)	0/4 (0%)	<b>1,000</b>

285 <sup>a</sup> The limit of detection by positive rate for each gene target is highlighted in bold286 <sup>b</sup> The final LoD was based on each manufacturer's results interpretation algorithm287 1. <sup>c</sup>Also includes presumptive positive results

288 **Table 2.** Clinical performance comparison of three sample-to-answer EUA molecular assays for the

Molecular Assay	Reference Standard <sup>a</sup>		(± 95% CI) <sup>bc</sup>		
	Positive	Negative	Kappa (κ) <sup>d</sup>	PPA	NPA
Xpert Xpress	Positive	57	0	98.3%	100%
	Negative	1	50	0.98 (1-0.95)	(0.91-1)
ID NOW <sup>e</sup>	Positive	50	0	87.7%	100%
	Negative	7	50	0.87 (0.96-0.78)	(0.76-0.95)
ePlex	Positive	53	0	91.4%	100%
	Negative	5	50	0.91 (0.99- 0.83)	(0.81-0.97)

289 detection of SARS-CoV-2 (n = 108).

290 <sup>a</sup>Reference standard was the Hologic Fusion assay.

291 <sup>b</sup>±, upper/lower 95%

292 <sup>c</sup>CI, confidence interval

293 <sup>d</sup>Almost-perfect (>0.90), strong (0.80 to 0.90), moderate (0.60 to 0.79), weak (0.40 to 0.59), minimal  
294 (0.21 to 0.39), or none (0 to 0.20).

295 <sup>e</sup>ID NOW had one Invalid that was removed from the analysis, which was positive by the reference

296 standard and the other two methods

297 **Table 3.** Details of discordant samples.

SARS-CoV-2 sample-to-answer molecular assay results and  
Ct values<sup>ab</sup>

SAMPLE ID	Reference Method		Xpert Xpress		ID NOW	ePlex
		Ct value		Ct value E/ N2		
<b>A-10</b>	<b>POS</b>	33.1	<b>POS</b>	32.8/35.8	<b>POS</b>	<b>NEG</b>
<b>A-12</b>	<b>POS</b>	33.2	<b>POS</b>	31.7/34.6	<b>NEG</b>	<b>NEG</b>
<b>A-14</b>	<b>POS</b>	34	<b>POS</b>	33.3/35.5	<b>NEG</b>	<b>NEG</b>
<b>A-15</b>	<b>POS</b>	32.6	<b>POS</b>	32.2/35.4	<b>NEG</b>	<b>POS</b>
<b>A-16</b>	<b>POS</b>	33.2	<b>POS</b>	33.6/36.4	<b>NEG</b>	<b>POS</b>
<b>A-24</b>	<b>POS</b>	38.5	<b>NEG</b>	N/A	<b>NEG</b>	<b>NEG</b>
<b>A-26</b>	<b>POS</b>	36.2	<b>POS</b>	36.6/39.5	<b>NEG</b>	<b>NEG</b>
<b>A-103</b>	<b>POS</b>	32	<b>POS</b>	31.1/34.3	<b>NEG</b>	<b>POS</b>

298 <sup>a</sup> Discordant sample results are highlighted in bold

299 <sup>b</sup> Ct, Cycle threshold

300 **Table 4.** Basic performance characteristics of three sample-to-answer EUA molecular SARS-CoV-2 assays  
301 evaluated.

	Xpert Xpress® SARS-CoV-2	ID NOW™ COVID-19	ePlex® SARS-CoV-2
Manufacturer	Cepheid	Abbott	GenMark
Sample type	NPS, nasal, mid-turbinate swab, nasal wash, nasal aspirate	NPS, NS, TS	NPS
Sample volume required (µl)	300	200	200
Extraction required	Yes (automated)	No	Yes (automated)
Detection platform/System	GeneXpert®, Xpress, Infinity	ID NOW™	ePlex®
Target region of SARS-CoV-2	N2, E	RdRp	N
Analytical sensitivity per claim	250 copies /mL	125 genome equivalents/mL	100,000 RNA transcript copies /mL
Maximum Throughput	4 per instrument (4-module configuration)	1 per instrument	6 per tower
Hands-on Time (per specimen)	~1 min	~2 min	~2 min
Assay Run Time	~45 min	<15 min	~ 90 min
User Results Interpretation	No	No	No
Overall Turn-around Time (per specimen)	~46 min	~17 min	~1.5 hr

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