

## 6. Clinical performance data

### 6.1 Clinical studies

- Report No: SJP20201022002
- Model: **DIAKEY COVID-19 Ag Rapid Test** - Issued date: 2020.10.22.
- Tested by: Kim Sanggyung (The Department of Diagnostic Medicine, Daegu Catholic University Hospital, Republic of KOREA)
- Reviewed by: Yoon Seonghoon
- Approved by: Chai Changsu
- Manufacturer: **SHINJIN MEDICS. INC**, 302-2, 401-2, 401-3, Ilsan Techno Town, 138, Ilsan-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, 10442, Republic of KOREA

#### 6.1.1 Test item

- Clinical trial to evaluate COVID-19 diagnostic reagents

#### 6.1.2 Product information

- DIAKEY COVID-19 Ag Rapid Test

#### 6.1.3 Kit used for test

Lot No.	Date of manufacture	Shelf life
E272001A01	2020.09.23	2021.09.23

#### 6.1.4 Preparation of sample

- 118 positive samples and 162 negative samples were collected from the samples that were diagnosed by the new Corona 19 SD biosensor, Inc. RT-PCR molecular diagnosis in the Department of Diagnostic Medicine, Daegu Catholic University Hospital.

#### 6.1.5 Transport medium information

- Manufacturer: Noble Biosciences, Inc.
- Model name: REST™ CTM (VTM)

#### 6.1.6 Reference product information

##### 6.1.6.1 Reference product

- Manufacturer: SD biosensor, Inc
- Address: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeak-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea
- Model name: STANDARD™ M CoV Real-Time Detection Kit
- Authorization number: No. 20-767

##### 6.1.6.2 Reference product intended Use

- In vitro diagnostic medicine device that helps diagnose SARS-CoV-2 virus infection by qualifying the SARS-CoV-2 gene (RdRp gene, E gene) in the upper and lower respiratory tract samples of patients with suspected respiratory infections disease using Real-time RT-PCR.

##### 6.1.6.3 Reference product principle

- Real-Time RT-PCR

### 6.1.7 Purpose of test

- The test is to evaluate the positive and negative coincidence rates of the DIAKEY COVID-19 Ag Rapid Test kit through performance comparison with RT-PCR reagent products, and to compare and confirm the performance.

### 6.1.8 Test criteria

- The DIAKEY COVID-19 Ag Rapid Kit is compared and tested using the negative and proton samples that have been tested with SD Biosensor STANDARD M nCoV Real-Time Detection Kit RT-PCR molecular diagnostic reagent at the Department of Laboratory Medicine, Daegu Catholic University Hospital.
- For the clinical performance test, reference RNA diagnosis was completed and 118 positive and 162 negative samples were compared and analyzed.
- When the antigen of the new coronavirus SARS-CoV-2 is present in the specimen, it binds to the antibody conjugate. The immune complex is then captured on the membrane by the pre-coated SARS-CoV-2 nucleocapsid protein monoclonal antibody, and a visible colored line will show up in the test line region indicating a positive result. In the absence of SARS-CoV-2 antigens, a colored line will not form in the test line region indicating a negative result.
- Test symbols: (+: positive, N: negative)

### 6.1.9 Test result

- The clinical evaluation results of 118 positive samples and 162 negative samples are as follows.

Negative 162 specimen (VTM), Store below -75°C						Positive 118 specimen (VTM), Store below -75°C							
No.	Specimen Collection Date	Day of RTPCR Test	Reference RTPCR		DIAKEY COVID-19 Ag	No.	Specimen Collection Date	Days after symptom onset	Day of RTPCR Test	Reference RT-PCR			DIAKEY COVID-19 Ag
			E / ORF1ab	IC (≤CT32)						E	ORF1ab	IC (≤CT32)	
1	2020.4.8	2020.4.8	N	24.96	N	1	2020.3.21	4	2020.3.21	25.42	24.11	24.32	+
2	2020.4.8	2020.4.8	N	23.91	N	2	2020.3.21	2	2020.3.21	19.28	20.67	23.31	+
3	2020.4.8	2020.4.8	N	23.71	N	3	2020.3.21	3	2020.3.21	15.34	17.81	22.10	+
4	2020.4.8	2020.4.8	N	24.19	N	4	2020.3.22	4	2020.3.22	21.36	23.64	24.33	+
5	2020.4.8	2020.4.8	N	24.94	N	5	2020.3.22	7	2020.3.22	22.21	22.89	24.19	+
6	2020.4.8	2020.4.8	N	25.37	N	6	2020.3.24	3	2020.3.24	26.31	27.22	23.37	+
7	2020.4.23	2020.4.23	N	24.11	N	7	2020.3.25	2	2020.3.25	24.36	25.31	24.36	+
8	2020.4.23	2020.4.23	N	25.17	N	8	2020.3.26	6	2020.3.26	18.31	19.11	24.13	+
9	2020.4.23	2020.4.23	N	24.28	N	9	2020.3.28	4	2020.3.28	20.33	22.41	25.77	+
10	2020.4.23	2020.4.23	N	25.03	N	10	2020.3.30	3	2020.3.30	19.74	20.33	26.39	+
11	2020.4.23	2020.4.23	N	24.61	N	11	2020.3.30	6	2020.3.30	26.31	27.22	24.69	+
12	2020.4.23	2020.4.23	N	25.38	N	12	2020.3.30	7	2020.3.30	22.11	24.36	25.31	+
13	2020.4.23	2020.4.23	N	24.72	N	13	2020.4.1	2	2020.4.1	23.66	24.91	25.88	+
14	2020.4.23	2020.4.23	N	25.92	N	14	2020.4.1	3	2020.4.1	20.32	21.61	24.71	+
15	2020.5.12	2020.5.12	N	24.88	N	15	2020.4.1	4	2020.4.1	17.84	18.61	23.67	+
16	2020.5.12	2020.5.12	N	23.15	N	16	2020.3.22	1	2020.3.22	26.31	28.11	24.61	+
17	2020.5.12	2020.5.12	N	22.92	N	17	2020.3.21	5	2020.3.21	25.63	26.71	22.74	+
18	2020.5.12	2020.5.12	N	24.67	N	18	2020.3.24	7	2020.3.24	27.99	28.72	23.78	+
19	2020.5.12	2020.5.12	N	23.08	N	19	2020.3.24	5	2020.3.26	21.64	24.71	23.91	+
20	2020.5.12	2020.5.12	N	24.72	N	20	2020.3.28	6	2020.3.28	24.62	25.14	24.28	+
21	2020.5.12	2020.5.12	N	24.66	N	21	2020.3.24	8	2020.3.24	31.22	32.35	24.09	N
22	2020.5.12	2020.5.12	N	24.54	N	22	2020.3.30	3	2020.3.30	17.32	18.69	23.19	+
23	2020.5.12	2020.5.12	N	23.18	N	23	2020.3.30	1	2020.3.30	19.32	22.34	22.33	+
24	2020.5.12	2020.5.12	N	24.01	N	24	2020.3.30	2	2020.3.30	24.99	26.31	24.41	+

25	2020.5.12	2020.5.12	N	23.75	N	25	2020.3.19	4	2020.3.21	22.47	23.91	24.77	+
26	2020.5.12	2020.5.12	N	24.34	N	26	2020.3.25	3	2020.3.25	24.82	26.37	22.52	+
27	2020.5.12	2020.5.12	N	22.90	N	27	2020.3.24	2	2020.3.26	17.31	18.64	23.41	+

28	2020.5.12	2020.5.12	N	23.44	N	28	2020.3.26	5	2020.3.28	22.94	24.38	24.01	+
29	2020.5.12	2020.5.12	N	24.72	N	29	2020.3.24	10	2020.3.24	30.33	31.41	22.72	N
30	2020.5.12	2020.5.12	N	23.93	N	30	2020.3.24	6	2020.3.26	18.32	19.54	21.74	+
31	2020.5.12	2020.5.12	N	22.31	N	31	2020.3.24	5	2020.3.26	20.13	21.36	23.54	+
32	2020.5.12	2020.5.12	N	21.36	N	32	2020.3.24	4	2020.3.26	18.36	20.36	25.53	+
33	2020.5.12	2020.5.12	N	24.63	N	33	2020.3.24	5	2020.3.26	19.36	21.34	25.35	+
34	2020.5.12	2020.5.12	N	23.21	N	34	2020.3.25	3	2020.3.26	19.36	22.69	23.86	+
35	2020.5.12	2020.5.12	N	22.78	N	35	2020.3.25	2	2020.3.26	20.14	22.47	22.85	+
36	2020.5.12	2020.5.12	N	22.67	N	36	2020.3.25	4	2020.3.26	15.17	17.41	24.35	+
37	2020.5.12	2020.5.12	N	22.19	N	37	2020.3.25	1	2020.3.26	21.30	23.91	23.47	+
38	2020.5.12	2020.5.12	N	21.39	N	38	2020.3.25	2	2020.3.27	21.39	22.10	22.98	+
39	2020.5.12	2020.5.12	N	24.19	N	39	2020.3.26	1	2020.3.28	24.21	25.98	22.95	+
40	2020.5.12	2020.5.12	N	23.91	N	40	2020.3.26	5	2020.3.26	21.36	23.66	25.69	+
41	2020.5.12	2020.5.12	N	22.66	N	41	2020.3.26	3	2020.3.26	19.33	22.14	25.28	+
42	2020.5.12	2020.5.12	N	22.73	N	42	2020.3.26	4	2020.3.26	20.91	22.31	25.12	+
43	2020.5.12	2020.5.12	N	22.64	N	43	2020.3.26	2	2020.3.26	20.14	22.91	25.01	+
44	2020.5.12	2020.5.12	N	22.33	N	44	2020.3.26	2	2020.3.26	18.24	20.10	22.75	+
45	2020.5.12	2020.5.12	N	23.62	N	45	2020.3.26	3	2020.3.26	17.34	19.71	26.03	+
46	2020.5.12	2020.5.12	N	23.21	N	46	2020.3.26	4	2020.3.26	20.14	22.46	25.31	+
47	2020.5.12	2020.5.12	N	25.60	N	47	2020.3.19	3	2020.3.21	21.92	23.64	22.31	+
48	2020.5.12	2020.5.12	N	24.23	N	48	2020.3.19	2	2020.3.21	22.14	23.64	23.34	+
49	2020.5.12	2020.5.12	N	23.35	N	49	2020.3.19	4	2020.3.21	25.91	26.30	25.64	+
50	2020.5.12	2020.5.12	N	23.63	N	50	2020.3.19	1	2020.3.21	26.41	28.72	25.29	+
51	2020.5.12	2020.5.12	N	22.18	N	51	2020.3.19	10	2020.3.21	31.21	32.19	23.23	N
52	2020.5.12	2020.5.12	N	24.05	N	52	2020.3.28	9	2020.3.30	30.19	32.47	24.59	N
53	2020.5.12	2020.5.12	N	23.10	N	53	2020.3.28	3	2020.3.30	21.31	23.10	25.65	+
54	2020.5.12	2020.5.12	N	26.75	N	54	2020.3.28	2	2020.3.30	19.63	20.78	23.91	+
55	2020.5.12	2020.5.12	N	25.15	N	55	2020.3.28	3	2020.3.30	22.31	25.14	22.35	+
56	2020.5.12	2020.5.12	N	25.01	N	56	2020.3.28	4	2020.3.30	24.12	26.34	24.33	+
57	2020.5.12	2020.5.12	N	26.82	N	57	2020.3.28	2	2020.3.30	18.32	21.39	22.98	+
58	2020.5.12	2020.5.12	N	25.39	N	58	2020.3.28	3	2020.3.30	22.31	23.24	26.26	+
59	2020.5.12	2020.5.12	N	22.58	N	59	2020.3.28	1	2020.3.30	24.14	27.84	24.89	+
60	2020.5.12	2020.5.12	N	24.65	N	60	2020.3.28	5	2020.3.30	22.92	23.01	26.26	+
61	2020.5.14	2020.5.14	N	24.11	N	61	2020.3.28	4	2020.3.30	21.45	22.39	25.33	+
62	2020.5.14	2020.5.14	N	23.99	N	62	2020.3.20	2	2020.3.22	22.61	23.72	24.14	+
63	2020.5.14	2020.5.14	N	22.96	N	63	2020.3.28	4	2020.3.30	23.44	25.03	22.13	+
64	2020.5.14	2020.5.14	N	22.24	N	64	2020.3.29	3	2020.3.29	20.97	22.98	25.61	+
65	2020.5.14	2020.5.14	N	25.42	N	65	2020.4.1	4	2020.4.1	21.33	23.88	23.21	+
66	2020.5.14	2020.5.14	N	23.83	N	66	2020.3.28	1	2020.3.30	22.53	24.28	22.87	+
67	2020.5.14	2020.5.14	N	22.37	N	67	2020.4.1	1	2020.4.3	19.64	22.61	23.64	+
68	2020.5.14	2020.5.14	N	22.97	N	68	2020.4.1	2	2020.4.3	18.55	20.74	24.91	+
69	2020.5.14	2020.5.14	N	23.96	N	69	2020.3.24	1	2020.3.26	19.55	20.14	23.19	+
70	2020.5.14	2020.5.14	N	26.38	N	70	2020.3.24	4	2020.3.26	22.13	25.41	22.53	+
71	2020.5.14	2020.5.14	N	24.70	N	71	2020.3.24	3	2020.3.24	24.21	26.43	24.55	+
72	2020.5.14	2020.5.14	N	25.14	N	72	2020.3.24	2	2020.3.24	18.23	21.93	22.89	+
73	2020.5.17	2020.5.17	N	23.33	N	73	2020.3.24	5	2020.3.24	22.13	23.42	26.64	+

<b>74</b>	2020.5.17	2020.5.17	N	22.53	N	<b>74</b>	2020.3.28	7	2020.3.28	24.41	27.85	24.98	+
<b>75</b>	2020.5.17	2020.5.17	N	24.64	N	<b>75</b>	2020.3.28	6	2020.3.28	22.29	23.20	26.27	+
<b>76</b>	2020.5.17	2020.5.17	N	23.97	N	<b>76</b>	2020.3.28	7	2020.3.28	21.54	22.94	25.26	+
<b>77</b>	2020.5.17	2020.5.17	N	25.68	N	<b>77</b>	2020.3.28	5	2020.3.30	22.61	23.72	24.16	+
<b>78</b>	2020.5.17	2020.5.17	N	26.74	N	<b>78</b>	2020.3.28	5	2020.3.30	23.46	25.13	22.14	+
<b>79</b>	2020.5.17	2020.5.17	N	24.38	N	<b>79</b>	2020.3.28	2	2020.3.28	20.98	22.55	25.54	+

<b>80</b>	2020.5.17	2020.5.17	N	26.30	N	<b>80</b>	2020.3.28	1	2020.3.28	21.13	22.78	23.12	+
<b>81</b>	2020.5.17	2020.5.17	N	26.27	N	<b>81</b>	2020.3.28	3	2020.3.28	21.41	23.52	24.43	+
<b>82</b>	2020.5.17	2020.5.17	N	26.11	N	<b>82</b>	2020.3.28	4	2020.3.30	23.51	24.31	22.89	+
<b>83</b>	2020.5.17	2020.5.17	N	24.41	N	<b>83</b>	2020.3.28	6	2020.3.30	20.97	22.14	25.22	+
<b>84</b>	2020.5.17	2020.5.17	N	24.58	N	<b>84</b>	2020.3.28	7	2020.3.28	21.15	23.89	23.11	+
<b>85</b>	2020.5.17	2020.5.17	N	22.13	N	<b>85</b>	2020.3.22	9	2020.3.22	23.15	24.12	22.51	+
<b>86</b>	2020.5.17	2020.5.17	N	26.05	N	<b>86</b>	2020.3.22	3	2020.3.22	20.13	21.14	24.82	+
<b>87</b>	2020.5.17	2020.5.17	N	25.71	N	<b>87</b>	2020.3.22	4	2020.3.24	21.83	22.14	24.12	+
<b>88</b>	2020.5.17	2020.5.17	N	22.64	N	<b>88</b>	2020.3.22	5	2020.3.24	20.41	22.19	25.10	+
<b>89</b>	2020.5.17	2020.5.17	N	24.76	N	<b>89</b>	2020.3.22	6	2020.3.24	18.25	20.07	22.57	+
<b>90</b>	2020.5.17	2020.5.17	N	23.66	N	<b>90</b>	2020.3.22	7	2020.3.22	17.51	19.17	26.03	+
<b>91</b>	2020.5.17	2020.5.17	N	24.71	N	<b>91</b>	2020.3.22	2	2020.3.22	20.11	22.25	25.31	+
<b>92</b>	2020.5.17	2020.5.17	N	23.79	N	<b>92</b>	2020.3.22	4	2020.3.22	21.29	23.24	22.13	+
<b>93</b>	2020.5.17	2020.5.17	N	26.54	N	<b>93</b>	2020.3.22	3	2020.3.22	22.13	23.54	23.55	+
<b>94</b>	2020.5.17	2020.5.17	N	22.14	N	<b>94</b>	2020.3.22	2	2020.3.22	25.19	26.14	25.46	+
<b>95</b>	2020.5.17	2020.5.17	N	25.54	N	<b>95</b>	2020.3.25	1	2020.3.25	26.17	28.27	25.22	+
<b>96</b>	2020.5.17	2020.5.17	N	26.71	N	<b>96</b>	2020.3.25	1	2020.3.25	22.12	24.63	25.11	+
<b>97</b>	2020.5.17	2020.5.17	N	24.67	N	<b>97</b>	2020.3.25	2	2020.3.25	23.25	24.54	25.90	+
<b>98</b>	2020.5.17	2020.5.17	N	25.51	N	<b>98</b>	2020.3.25	1	2020.3.25	20.24	21.61	24.71	+
<b>99</b>	2020.5.17	2020.5.17	N	23.32	N	<b>99</b>	2020.3.25	3	2020.3.25	17.48	18.59	23.24	+
<b>100</b>	2020.5.17	2020.5.17	N	23.64	N	<b>100</b>	2020.3.25	4	2020.3.25	26.13	28.46	24.55	+
<b>101</b>	2020.5.17	2020.5.17	N	24.49	N	<b>101</b>	2020.3.25	3	2020.3.25	20.61	21.49	24.42	+
<b>102</b>	2020.5.17	2020.5.17	N	25.38	N	<b>102</b>	2020.3.25	8	2020.3.25	20.42	22.16	23.17	+
<b>103</b>	2020.5.17	2020.5.17	N	26.14	N	<b>103</b>	2020.3.25	3	2020.3.25	20.41	21.63	23.55	+
<b>104</b>	2020.5.17	2020.5.17	N	22.79	N	<b>104</b>	2020.3.25	2	2020.3.25	18.73	20.63	25.49	+
<b>105</b>	2020.5.17	2020.5.17	N	23.91	N	<b>105</b>	2020.4.1	2	2020.4.1	19.45	21.64	25.55	+
<b>106</b>	2020.5.17	2020.5.17	N	24.65	N	<b>106</b>	2020.4.1	3	2020.4.1	19.55	22.55	23.71	+
<b>107</b>	2020.5.17	2020.5.17	N	25.87	N	<b>107</b>	2020.4.1	5	2020.4.3	20.15	22.64	22.99	+
<b>108</b>	2020.5.17	2020.5.17	N	24.71	N	<b>108</b>	2020.4.1	4	2020.4.3	15.18	17.65	24.24	+
<b>109</b>	2020.5.17	2020.5.17	N	23.98	N	<b>109</b>	2020.4.1	2	2020.4.3	21.44	23.56	23.55	+
<b>110</b>	2020.5.17	2020.5.17	N	25.61	N	<b>110</b>	2020.4.1	3	2020.4.3	21.42	22.25	22.20	+
<b>111</b>	2020.5.17	2020.5.17	N	26.72	N	<b>111</b>	2020.4.1	2	2020.4.1	20.46	22.94	22.38	+
<b>112</b>	2020.5.17	2020.5.17	N	22.79	N	<b>112</b>	2020.3.26	3	2020.3.26	25.91	26.41	25.64	+
<b>113</b>	2020.5.17	2020.5.17	N	24.51	N	<b>113</b>	2020.3.26	5	2020.3.26	26.71	28.72	25.25	+
<b>114</b>	2020.5.17	2020.5.17	N	23.65	N	<b>114</b>	2020.3.26	4	2020.3.26	22.42	24.36	25.12	+
<b>115</b>	2020.5.17	2020.5.17	N	22.79	N	<b>115</b>	2020.3.26	2	2020.3.26	23.52	24.43	25.09	+
<b>116</b>	2020.5.17	2020.5.17	N	24.87	N	<b>116</b>	2020.3.26	4	2020.3.26	17.84	18.95	23.42	+
<b>117</b>	2020.5.17	2020.5.17	N	25.34	N	<b>117</b>	2020.3.26	10	2020.3.26	22.24	25.63	24.46	+
<b>118</b>	2020.5.17	2020.5.17	N	24.36	N	<b>118</b>	2020.3.26	3	2020.3.26	22.64	24.59	25.54	+
<b>119</b>	2020.5.17	2020.5.17	N	24.74	N								



COVID-19 specimen (Medium: VTM)		Reference RT-PCR		
		Positive	Negative	Total
DIAKEY COVID-19 Ag Rapid Test	Positive	114	0	114
	Negative	4	162	166
Total		118	162	280
● Positive percent agreement, PPA		= 96.6% (114/118), (95% CI: 91.6% - 98.7%)		
● Negative percent agreement, NPA		= 100% (162/162), (95% CI: 97.7% - 100%)		
● Total percent agreement		= 98.6% {(114+162) / 280}, (95% CI: 96.4% - 99.4 %)		

### 6.1.10 Conclusion

- The performance evaluation of the SD Biosensor RT-PCR test and the DIAKEY COVID-19 Ag Rapid Test, which was compared and analyzed, shows the results as follows.

Positive percent agreement (%)	Negative percent agreement (%)	Overall percent agreement (%)
<b>96.6</b>	<b>100</b>	<b>98.6</b>

- For rapid detection of SARS-CoV-2 antigen, the DIAKEY COVID-19 Ag Rapid Test was evaluated in the Department of Diagnostic Laboratory Medicine, Catholic University of Daegu Hospital. Residual samples were tested in VTM transport medium and compared with RT-PCR results. The DIAKEY COVID-19 Ag Rapid Test showed a high agreement rate of 100% in 162 negative samples whose Ct value was not measured by RT-PCR. The positive 118 samples showed a 96.6% agreement rate, and the lower the Ct value, the better the agreement rate.
- If it is impossible to diagnose by RT-PCR at the time of the COVID-19 pandemic, the DIAKEY COVID-19 Ag Rapid Test is considered to be of high clinical value due to rapid diagnosis.

## Clinical Performance Test Report

### I . Clinical performance test plan

#### 1. Introduction

##### 1) Investigator:

Kim Sanggyung (the Department of Diagnostic Medicine, Daegu Catholic University Hospital)

##### 2) Sponsor:

Shinjin Medics, Inc.

##### 3) Product name:

DIAKEY COVID-19 Ag Rapid Test

##### 4) Study name:

Evaluation of the detection of novel Coronavirus antigens by DIAKEY COVID-19 Ag Rapid Test reagent

##### 5) Purpose of test:

The DIAKEY COVID-19 Ag Rapid Test is aimed at reducing the risk of further spreading through rapid immunological diagnosis of novel coronavirus, predicting the spread of infection from unspecified masses and quarantining the infected person. Accordingly, the Department of Diagnostic Medicine, Daegu Catholic University Hospital, evaluates the DIAKEY COVID-19 Ag Rapid Test reagent to confirm its clinical performance.

##### 6) Measurement principle and method:

The Test is a lateral flow immunochromatographic assay based on the principle of the double antibody-sandwich technique using two pre-coated lines of control line (C) and test line (T) on the surface of the nitrocellulose membrane. Both lines in the result window are not visible before testing.

Monoclonal mouse anti-SARS-CoV-2 antibody is coated on the test line region and goat antimouse IgG on the control line, respectively. When the test specimen is applied to the specimen well (S), a specimen migrates upward by capillary action.

The SARS-CoV-2 antigens if present in the specimen will react with monoclonal mouse antiSARS-CoV-2 antibody making an immune complex. The complex is then captured on the membrane by the pre-coated monoclonal mouse anti-SARS-CoV-2 antibody making antigenantibody color particle complex, and a visible colored line will show up in the test line region indicating a positive result.

In the absence of SARS-CoV-2 antigens, a colored line will not form in the test line region indicating a negative result.

The solution continues to migrate to encounter a control reagent that binds a control conjugate. To serve as a procedural control, a colored line will always appear at the control line region, indicating that the test is performed properly and the test reagents of the control line are working.



## 2. Specimen informance

### 1) Kit used for test: DIAKEY COVID-19 Ag Rapid Kit

Lot No.	Date of manufacture	Shelf life
E272001A01	2020.9.23	2021.9.23

### 2) Preparation of sample:

#### 2-1) negative and positive sample:

The Department of Diagnostic Medicine, Daegu Catholic University Hospital, selects 162 negative and 118 positive specimens that have been tested by the new corona 19 RT-PCR molecular diagnosis. The sample is tested with the remaining NPS samples stored in VTM(Viral Transport Medium) stored below -75°C.

## 3. Study method

The DIAKEY COVID-19 Ag Rapid Kit is compared and tested using the negative and proton samples that have been tested with SD Biosensor STANDARD M nCoV Real-Time Detection Kit RT-PCR molecular diagnostic reagent at the Department of Laboratory Medicine, Daegu Catholic University Hospital. For the clinical performance test, reference RNA diagnosis was completed and 118 positive and 162 negative samples were compared and analyzed. When the antigen of the new coronavirus SARS-CoV-2 is present in the specimen, it binds to the antibody conjugate. The immune complex is then captured on the membrane by the pre-coated SARSCoV-2 nucleocapsid protein monoclonal antibody, and a visible colored line will show up in the test line region indicating a positive result. In the absence of SARS-CoV-2 antigens, a colored line will not form in the test line region indicating a negative result.

## 4. Investigator

Organization: Daegu Catholic University Hospital, Department of Diagnostic Medicine Name:

Kim Sanggyung (sign) 

## 5. Test date

2020. 10. 21.

## II . Clinical performance test result report

- Test symbol: (N: negative, +: positive)

### 1. Test result

Negative 162 specimen (VTM), Store below -75°C						Positive 118 specimen (VTM), Store below -75°C							
No.	Specimen Collection Date	Day of RTPCR Test	Reference RTPCR		DIAKEY COVID-19 Ag	No.	Specimen Collection Date	Days after symptom onset	Day of RTPCR Test	Reference RT-PCR			DIAKEY COVID-19 Ag
			E / ORF1ab	IC (≤CT32)						E	ORF1a b	IC (≤CT32)	
1	2020.4.8	2020.4.8	N	24.96	N	1	2020.3.21	4	2020.3.21	25.42	24.11	24.32	+
2	2020.4.8	2020.4.8	N	23.91	N	2	2020.3.21	2	2020.3.21	19.28	20.67	23.31	+
3	2020.4.8	2020.4.8	N	23.71	N	3	2020.3.21	3	2020.3.21	15.34	17.81	22.10	+





4	2020.4.8	2020.4.8	N	24.19	N	4	2020.3.22	4	2020.3.22	21.36	23.64	24.33	+
5	2020.4.8	2020.4.8	N	24.94	N	5	2020.3.22	7	2020.3.22	22.21	22.89	24.19	+
6	2020.4.8	2020.4.8	N	25.37	N	6	2020.3.24	3	2020.3.24	26.31	27.22	23.37	+
7	2020.4.23	2020.4.23	N	24.11	N	7	2020.3.25	2	2020.3.25	24.36	25.31	24.36	+
8	2020.4.23	2020.4.23	N	25.17	N	8	2020.3.26	6	2020.3.26	18.31	19.11	24.13	+
9	2020.4.23	2020.4.23	N	24.28	N	9	2020.3.28	4	2020.3.28	20.33	22.41	25.77	+
10	2020.4.23	2020.4.23	N	25.03	N	10	2020.3.30	3	2020.3.30	19.74	20.33	26.39	+
11	2020.4.23	2020.4.23	N	24.61	N	11	2020.3.30	6	2020.3.30	26.31	27.22	24.69	+
12	2020.4.23	2020.4.23	N	25.38	N	12	2020.3.30	7	2020.3.30	22.11	24.36	25.31	+
13	2020.4.23	2020.4.23	N	24.72	N	13	2020.4.1	2	2020.4.1	23.66	24.91	25.88	+
14	2020.4.23	2020.4.23	N	25.92	N	14	2020.4.1	3	2020.4.1	20.32	21.61	24.71	+
15	2020.5.12	2020.5.12	N	24.88	N	15	2020.4.1	4	2020.4.1	17.84	18.61	23.67	+
16	2020.5.12	2020.5.12	N	23.15	N	16	2020.3.22	1	2020.3.22	26.31	28.11	24.61	+
17	2020.5.12	2020.5.12	N	22.92	N	17	2020.3.21	5	2020.3.21	25.63	26.71	22.74	+
18	2020.5.12	2020.5.12	N	24.67	N	18	2020.3.24	7	2020.3.24	27.99	28.72	23.78	+
19	2020.5.12	2020.5.12	N	23.08	N	19	2020.3.24	5	2020.3.26	21.64	24.71	23.91	+
20	2020.5.12	2020.5.12	N	24.72	N	20	2020.3.28	6	2020.3.28	24.62	25.14	24.28	+
21	2020.5.12	2020.5.12	N	24.66	N	21	2020.3.24	8	2020.3.24	31.22	32.35	24.09	N
22	2020.5.12	2020.5.12	N	24.54	N	22	2020.3.30	3	2020.3.30	17.32	18.69	23.19	+
23	2020.5.12	2020.5.12	N	23.18	N	23	2020.3.30	1	2020.3.30	19.32	22.34	22.33	+
24	2020.5.12	2020.5.12	N	24.01	N	24	2020.3.30	2	2020.3.30	24.99	26.31	24.41	+
25	2020.5.12	2020.5.12	N	23.75	N	25	2020.3.19	4	2020.3.21	22.47	23.91	24.77	+
26	2020.5.12	2020.5.12	N	24.34	N	26	2020.3.25	3	2020.3.25	24.82	26.37	22.52	+
27	2020.5.12	2020.5.12	N	22.90	N	27	2020.3.24	2	2020.3.26	17.31	18.64	23.41	+
28	2020.5.12	2020.5.12	N	23.44	N	28	2020.3.26	5	2020.3.28	22.94	24.38	24.01	+
29	2020.5.12	2020.5.12	N	24.72	N	29	2020.3.24	10	2020.3.24	30.33	31.41	22.72	N
30	2020.5.12	2020.5.12	N	23.93	N	30	2020.3.24	6	2020.3.26	18.32	19.54	21.74	+
31	2020.5.12	2020.5.12	N	22.31	N	31	2020.3.24	5	2020.3.26	20.13	21.36	23.54	+
32	2020.5.12	2020.5.12	N	21.36	N	32	2020.3.24	4	2020.3.26	18.36	20.36	25.53	+
33	2020.5.12	2020.5.12	N	24.63	N	33	2020.3.24	5	2020.3.26	19.36	21.34	25.35	+
34	2020.5.12	2020.5.12	N	23.21	N	34	2020.3.25	3	2020.3.26	19.36	22.69	23.86	+
35	2020.5.12	2020.5.12	N	22.78	N	35	2020.3.25	2	2020.3.26	20.14	22.47	22.85	+
36	2020.5.12	2020.5.12	N	22.67	N	36	2020.3.25	4	2020.3.26	15.17	17.41	24.35	+
37	2020.5.12	2020.5.12	N	22.19	N	37	2020.3.25	1	2020.3.26	21.30	23.91	23.47	+
38	2020.5.12	2020.5.12	N	21.39	N	38	2020.3.25	2	2020.3.27	21.39	22.10	22.98	+
39	2020.5.12	2020.5.12	N	24.19	N	39	2020.3.26	1	2020.3.28	24.21	25.98	22.95	+
40	2020.5.12	2020.5.12	N	23.91	N	40	2020.3.26	5	2020.3.26	21.36	23.66	25.69	+
41	2020.5.12	2020.5.12	N	22.66	N	41	2020.3.26	3	2020.3.26	19.33	22.14	25.28	+
42	2020.5.12	2020.5.12	N	22.73	N	42	2020.3.26	4	2020.3.26	20.91	22.31	25.12	+

43	2020.5.12	2020.5.12	N	22.64	N	43	2020.3.26	2	2020.3.26	20.14	22.91	25.01	+
44	2020.5.12	2020.5.12	N	22.33	N	44	2020.3.26	2	2020.3.26	18.24	20.10	22.75	+
45	2020.5.12	2020.5.12	N	23.62	N	45	2020.3.26	3	2020.3.26	17.34	19.71	26.03	+
46	2020.5.12	2020.5.12	N	23.21	N	46	2020.3.26	4	2020.3.26	20.14	22.46	25.31	+
47	2020.5.12	2020.5.12	N	25.60	N	47	2020.3.19	3	2020.3.21	21.92	23.64	22.31	+
48	2020.5.12	2020.5.12	N	24.23	N	48	2020.3.19	2	2020.3.21	22.14	23.64	23.34	+
49	2020.5.12	2020.5.12	N	23.35	N	49	2020.3.19	4	2020.3.21	25.91	26.30	25.64	+
50	2020.5.12	2020.5.12	N	23.63	N	50	2020.3.19	1	2020.3.21	26.41	28.72	25.29	+



51	2020.5.12	2020.5.12	N	22.18	N	51	2020.3.19	10	2020.3.21	31.21	32.19	23.23	N
52	2020.5.12	2020.5.12	N	24.05	N	52	2020.3.28	9	2020.3.30	30.19	32.47	24.59	N
53	2020.5.12	2020.5.12	N	23.10	N	53	2020.3.28	3	2020.3.30	21.31	23.10	25.65	+
54	2020.5.12	2020.5.12	N	26.75	N	54	2020.3.28	2	2020.3.30	19.63	20.78	23.91	+
55	2020.5.12	2020.5.12	N	25.15	N	55	2020.3.28	3	2020.3.30	22.31	25.14	22.35	+
56	2020.5.12	2020.5.12	N	25.01	N	56	2020.3.28	4	2020.3.30	24.12	26.34	24.33	+
57	2020.5.12	2020.5.12	N	26.82	N	57	2020.3.28	2	2020.3.30	18.32	21.39	22.98	+
58	2020.5.12	2020.5.12	N	25.39	N	58	2020.3.28	3	2020.3.30	22.31	23.24	26.26	+
59	2020.5.12	2020.5.12	N	22.58	N	59	2020.3.28	1	2020.3.30	24.14	27.84	24.89	+
60	2020.5.12	2020.5.12	N	24.65	N	60	2020.3.28	5	2020.3.30	22.92	23.01	26.26	+
61	2020.5.14	2020.5.14	N	24.11	N	61	2020.3.28	4	2020.3.30	21.45	22.39	25.33	+
62	2020.5.14	2020.5.14	N	23.99	N	62	2020.3.20	2	2020.3.22	22.61	23.72	24.14	+
63	2020.5.14	2020.5.14	N	22.96	N	63	2020.3.28	4	2020.3.30	23.44	25.03	22.13	+
64	2020.5.14	2020.5.14	N	22.24	N	64	2020.3.29	3	2020.3.29	20.97	22.98	25.61	+
65	2020.5.14	2020.5.14	N	25.42	N	65	2020.4.1	4	2020.4.1	21.33	23.88	23.21	+
66	2020.5.14	2020.5.14	N	23.83	N	66	2020.3.28	1	2020.3.30	22.53	24.28	22.87	+
67	2020.5.14	2020.5.14	N	22.37	N	67	2020.4.1	1	2020.4.3	19.64	22.61	23.64	+
68	2020.5.14	2020.5.14	N	22.97	N	68	2020.4.1	2	2020.4.3	18.55	20.74	24.91	+
69	2020.5.14	2020.5.14	N	23.96	N	69	2020.3.24	1	2020.3.26	19.55	20.14	23.19	+
70	2020.5.14	2020.5.14	N	26.38	N	70	2020.3.24	4	2020.3.26	22.13	25.41	22.53	+
71	2020.5.14	2020.5.14	N	24.70	N	71	2020.3.24	3	2020.3.24	24.21	26.43	24.55	+
72	2020.5.14	2020.5.14	N	25.14	N	72	2020.3.24	2	2020.3.24	18.23	21.93	22.89	+
73	2020.5.17	2020.5.17	N	23.33	N	73	2020.3.24	5	2020.3.24	22.13	23.42	26.64	+
74	2020.5.17	2020.5.17	N	22.53	N	74	2020.3.28	7	2020.3.28	24.41	27.85	24.98	+
75	2020.5.17	2020.5.17	N	24.64	N	75	2020.3.28	6	2020.3.28	22.29	23.20	26.27	+
76	2020.5.17	2020.5.17	N	23.97	N	76	2020.3.28	7	2020.3.28	21.54	22.94	25.26	+
77	2020.5.17	2020.5.17	N	25.68	N	77	2020.3.28	5	2020.3.30	22.61	23.72	24.16	+
78	2020.5.17	2020.5.17	N	26.74	N	78	2020.3.28	5	2020.3.30	23.46	25.13	22.14	+
79	2020.5.17	2020.5.17	N	24.38	N	79	2020.3.28	2	2020.3.28	20.98	22.55	25.54	+
80	2020.5.17	2020.5.17	N	26.30	N	80	2020.3.28	1	2020.3.28	21.13	22.78	23.12	+
81	2020.5.17	2020.5.17	N	26.27	N	81	2020.3.28	3	2020.3.28	21.41	23.52	24.43	+
82	2020.5.17	2020.5.17	N	26.11	N	82	2020.3.28	4	2020.3.30	23.51	24.31	22.89	+
83	2020.5.17	2020.5.17	N	24.41	N	83	2020.3.28	6	2020.3.30	20.97	22.14	25.22	+
84	2020.5.17	2020.5.17	N	24.58	N	84	2020.3.28	7	2020.3.28	21.15	23.89	23.11	+
85	2020.5.17	2020.5.17	N	22.13	N	85	2020.3.22	9	2020.3.22	23.15	24.12	22.51	+
86	2020.5.17	2020.5.17	N	26.05	N	86	2020.3.22	3	2020.3.22	20.13	21.14	24.82	+
87	2020.5.17	2020.5.17	N	25.71	N	87	2020.3.22	4	2020.3.24	21.83	22.14	24.12	+
88	2020.5.17	2020.5.17	N	22.64	N	88	2020.3.22	5	2020.3.24	20.41	22.19	25.10	+
89	2020.5.17	2020.5.17	N	24.76	N	89	2020.3.22	6	2020.3.24	18.25	20.07	22.57	+
90	2020.5.17	2020.5.17	N	23.66	N	90	2020.3.22	7	2020.3.22	17.51	19.17	26.03	+
91	2020.5.17	2020.5.17	N	24.71	N	91	2020.3.22	2	2020.3.22	20.11	22.25	25.31	+
92	2020.5.17	2020.5.17	N	23.79	N	92	2020.3.22	4	2020.3.22	21.29	23.24	22.13	+
93	2020.5.17	2020.5.17	N	26.54	N	93	2020.3.22	3	2020.3.22	22.13	23.54	23.55	+
94	2020.5.17	2020.5.17	N	22.14	N	94	2020.3.22	2	2020.3.22	25.19	26.14	25.46	+
95	2020.5.17	2020.5.17	N	25.54	N	95	2020.3.25	1	2020.3.25	26.17	28.27	25.22	+
96	2020.5.17	2020.5.17	N	26.71	N	96	2020.3.25	1	2020.3.25	22.12	24.63	25.11	+
97	2020.5.17	2020.5.17	N	24.67	N	97	2020.3.25	2	2020.3.25	23.25	24.54	25.90	+



98	2020.5.17	2020.5.17	N	25.51	N	98	2020.3.25	1	2020.3.25	20.24	21.61	24.71	+
99	2020.5.17	2020.5.17	N	23.32	N	99	2020.3.25	3	2020.3.25	17.48	18.59	23.24	+
100	2020.5.17	2020.5.17	N	23.64	N	100	2020.3.25	4	2020.3.25	26.13	28.46	24.55	+
101	2020.5.17	2020.5.17	N	24.49	N	101	2020.3.25	3	2020.3.25	20.61	21.49	24.42	+
102	2020.5.17	2020.5.17	N	25.38	N	102	2020.3.25	8	2020.3.25	20.42	22.16	23.17	+
103	2020.5.17	2020.5.17	N	26.14	N	103	2020.3.25	3	2020.3.25	20.41	21.63	23.55	+
104	2020.5.17	2020.5.17	N	22.79	N	104	2020.3.25	2	2020.3.25	18.73	20.63	25.49	+
105	2020.5.17	2020.5.17	N	23.91	N	105	2020.4.1	2	2020.4.1	19.45	21.64	25.55	+
106	2020.5.17	2020.5.17	N	24.65	N	106	2020.4.1	3	2020.4.1	19.55	22.55	23.71	+
107	2020.5.17	2020.5.17	N	25.87	N	107	2020.4.1	5	2020.4.3	20.15	22.64	22.99	+
108	2020.5.17	2020.5.17	N	24.71	N	108	2020.4.1	4	2020.4.3	15.18	17.65	24.24	+
109	2020.5.17	2020.5.17	N	23.98	N	109	2020.4.1	2	2020.4.3	21.44	23.56	23.55	+
110	2020.5.17	2020.5.17	N	25.61	N	110	2020.4.1	3	2020.4.3	21.42	22.25	22.20	+
111	2020.5.17	2020.5.17	N	26.72	N	111	2020.4.1	2	2020.4.1	20.46	22.94	22.38	+
112	2020.5.17	2020.5.17	N	22.79	N	112	2020.3.26	3	2020.3.26	25.91	26.41	25.64	+
113	2020.5.17	2020.5.17	N	24.51	N	113	2020.3.26	5	2020.3.26	26.71	28.72	25.25	+
114	2020.5.17	2020.5.17	N	23.65	N	114	2020.3.26	4	2020.3.26	22.42	24.36	25.12	+
115	2020.5.17	2020.5.17	N	22.79	N	115	2020.3.26	2	2020.3.26	23.52	24.43	25.09	+
116	2020.5.17	2020.5.17	N	24.87	N	116	2020.3.26	4	2020.3.26	17.84	18.95	23.42	+
117	2020.5.17	2020.5.17	N	25.34	N	117	2020.3.26	10	2020.3.26	22.24	25.63	24.46	+
118	2020.5.17	2020.5.17	N	24.36	N	118	2020.3.26	3	2020.3.26	22.64	24.59	25.54	+
119	2020.5.17	2020.5.17	N	24.74	N								
120	2020.5.17	2020.5.17	N	23.54	N								
121	2020.5.14	2020.5.14	N	22.81	N								
122	2020.5.14	2020.5.14	N	24.50	N								
123	2020.5.14	2020.5.14	N	22.01	N								
124	2020.5.14	2020.5.14	N	25.57	N								
125	2020.5.14	2020.5.14	N	25.51	N								
126	2020.5.14	2020.5.14	N	24.10	N								
127	2020.5.14	2020.5.14	N	25.28	N								
128	2020.5.14	2020.5.14	N	25.93	N								
129	2020.5.14	2020.5.14	N	22.85	N								
130	2020.5.12	2020.5.12	N	24.56	N								
131	2020.5.12	2020.5.12	N	23.11	N								
132	2020.5.12	2020.5.12	N	24.99	N								
133	2020.5.12	2020.5.12	N	22.69	N								
134	2020.5.12	2020.5.12	N	22.42	N								
135	2020.5.12	2020.5.12	N	25.24	N								
136	2020.5.12	2020.5.12	N	23.38	N								
137	2020.4.23	2020.4.23	N	22.73	N								
138	2020.4.23	2020.4.23	N	22.79	N								
139	2020.4.23	2020.4.23	N	24.91	N								
140	2020.4.23	2020.4.23	N	24.49	N								
141	2020.4.23	2020.4.23	N	25.73	N								
142	2020.4.23	2020.4.23	N	25.11	N								



143	2020.4.23	2020.4.23	N	25.71	N								
144	2020.4.23	2020.4.23	N	24.82	N								
145	2020.4.23	2020.4.23	N	25.30	N								
146	2020.4.23	2020.4.23	N	24.16	N								
147	2020.4.23	2020.4.23	N	25.83	N								
148	2020.4.23	2020.4.23	N	24.27	N								
149	2020.4.23	2020.4.23	N	25.29	N								
150	2020.4.23	2020.4.23	N	22.85	N								
151	2020.4.8	2020.4.8	N	23.51	N								
152	2020.4.8	2020.4.8	N	22.29	N								
153	2020.4.8	2020.4.8	N	24.76	N								
154	2020.4.8	2020.4.8	N	23.80	N								
155	2020.4.8	2020.4.8	N	24.27	N								
156	2020.4.8	2020.4.8	N	24.58	N								
157	2020.4.8	2020.4.8	N	23.94	N								
158	2020.4.8	2020.4.8	N	26.25	N								
159	2020.4.8	2020.4.8	N	25.78	N								
160	2020.4.8	2020.4.8	N	25.65	N								
161	2020.4.8	2020.4.8	N	23.41	N								
162	2020.4.8	2020.4.8	N	24.57	N								

COVID-19 specimen (Medium: VTM)		Reference RT-PCR		
		Positive	Negative	Total
DIAKEY COVID-19 Ag Rapid Test	Positive	114	0	114
	Negative	4	162	166
Total		118	162	280

- 1) Positive percent agreement = 96.6% (114/118), (95% CI: 91.6% - 98.7%)
- 2) Negative percent agreement = 100% (162/162), (95 CI: 97.7% - 100%)
- 3) Total percent agreement = 98.6% {(114+162) / 280}, (95% CI: 96.4% - 99.4%)

**Remaining Clinical Specimen Test Certificate**

**1. Issued date:** 2020.10.21.

**2. Title:** Clinical test certificate for evaluation of COVID-19 antigen immunodiagnostic reagent

**3. Test name:** Shinjin Medics, Inc., DIAKEY COVID-19 Ag Rapid Test

**4. Supply and test contents**

- 1) The Department of Diagnostic Medicine, Daegu Catholic University Hospital, conducted a clinical test in cooperation with Shinjin Medics, Inc. to determine whether the performance of domestic diagnostic reagents was suitable for export in relation to the WHO New Corona Pandemic Declaration.
- 2) Rapid diagnosis was evaluated within 15 minutes with the DIAKEY COVID-19 Ag Rapid Kit, and RT-PCR results and performance were compared with negative and positive samples determined by RT-PCR.

**5. Result:**

DIAKEY COVID-19 Ag Rapid Kit was evaluated for rapid detection of SARS-CoV-2 antigen in the Department of Diagnostic Medicine, Daegu Catholic University Hospital. The remaining samples were tested as VTM samples and compared with the RT-PCR results. The DIAKEY COVID-19 Ag Rapid Kit showed a high agreement rate of 100% in 162 samples that were negative for SARS-CoV-2 RT-PCR. The 118 positive samples showed a 96.6% agreement rate. Therefore, in situations where it is difficult to perform RT-PCR tests to diagnose SARS-CoV-2 infection, DIAKEY COVID-19 Ag Kit is considered to be of high clinical utility value due to rapid diagnosis.

**Organization:** Daegu Catholic University Hospital, Department of Diagnostic Medicine

**Investigator:** Department of Diagnostic Medicine, Kim Sanggyung  
(sign)



**Daegu Catholic University Hospital, Department of Diagnostic Medicine**

