





<b>MVZ Labor Dr. Quade und Kollegen</b>					
	<b>SOP</b>				
	<b>Comparison study for COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold) - Final report</b>				
	Doku-Nr.:	VA-500	Version:	1	Seite:

Replaces version:	
Change notice:	

### Table of contents

<b>1</b>	<b>AIM</b> .....	<b>3</b>
<b>2</b>	<b>MATERIAL</b> .....	<b>3</b>
2.1	Patient material.....	3
2.1.1	Preparation of the patient .....	3
2.1.2	Sample material.....	3
2.1.3	Sample container.....	3
2.1.4	Storage conditions.....	3
2.1.5	Sample preparation .....	3
2.2	Test strips .....	3
<b>3</b>	<b>RESPONSIBILITIES</b> .....	<b>5</b>
<b>4</b>	<b>WORKFLOW</b> .....	<b>5</b>
4.1	False negative rate of positive samples .....	5
4.1.1	Experimental operation.....	5
4.2	False positive rate of negative samples .....	5
4.2.1	Experimental operation.....	5
4.3	Persistence of signal interpretation (Signal stability).....	5
4.3.1	Purpose .....	5
4.3.2	Experimental materials .....	5
4.3.3	Experimental method.....	5
4.4	Convenience of operation.....	6
4.4.1	Purpose .....	6
4.4.2	Experimental materials .....	6
4.4.3	Experimental method.....	6
4.5	Evaluation of the difference in the amount of sample loaded on the reagent strip .....	6
4.5.1	Purpose .....	6
4.5.2	Experimental materials .....	6
4.5.3	Experimental method.....	6
4.6	Evaluation of positive sample signal and sensitivity.....	6
4.6.1	Purpose .....	6
4.6.2	Experimental material.....	6
4.6.3	Experimental method.....	6
4.7	Leakage safety of the sample.....	6
4.7.1	Experimental operation.....	6
4.8	Test signal of inactive virus .....	7

	Erstellt	Geprüft	Freigegeben
Name / Datum	Nicole Beisecker 	08.10.2021 Gabriele Dresen 	08.10.2021 Annegret Quade 




SOP

Comparison study for COVID-19 Antigen Sealing Tube Test Strip  
(Colloidal Gold)

Doku-Nr.:	VA-500	Version:	1	Seite:	2/14
-----------	--------	----------	---	--------	------

4.8.1 Experimental operation.....	7
<b>5 DOCUMENTATION.....</b>	<b>7</b>
5.1 Statistical evaluation.....	7
5.2 Comparison index.....	7
5.2.1 Comparison of the results of 75 positive samples (nasal secretions) tested by 4 products .....	7
5.2.2 Statistics of experimental results: Comparison table of false negative rates of test samples for four products .....	9
5.2.3 Example picture of positive test results .....	9
5.2.4 Comparison of the results of 20 negative samples (nasal secretions) tested by 4 products .....	10
5.2.5 Statistics of experimental results: Comparison table of false positive rates of test samples for four products .....	10
5.2.6 Example picture of negative test results.....	11
5.3 Persistence of signal interpretation (Signal stability).....	11
5.3.1 Interpretation table of response time persistence results for four product kits.....	11
5.4 Convenience of operation.....	12
5.4.1 Comparison of the time required to complete 10 samples of the four products.....	12
5.4.2 Ease of use.....	12
5.5 Evaluation of the difference in the amount of sample loaded on the reagent strip .....	12
5.5.1 Repeatability result judgment.....	12
5.6 Evaluation of positive sample signal and sensitivity.....	13
5.6.1 Comparison of test results of 4 products (Ct=16,6).....	13
<b>6 FINAL CONCLUSION.....</b>	<b>14</b>
<b>7 MODIFICATION SERVICE .....</b>	<b>14</b>
<b>8 SUPPLIED DOCUMENTS .....</b>	<b>14</b>
8.1.1 Manufacturer's test instructions.....	14

<b>MVZ Labor Dr. Quade und Kollegen</b>					
	<b>SOP</b>				
	<b>Comparsion study for COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold)</b>				
	Doku-Nr.:	VA-500	Version:	1	Seite:

## 1 Aim

Comparison test (Market study No. 21001) of Amazing Antigen COVID-19 Sealing Tube Test Strip Test. Compare the product performance indicators of the top 3 healthcare companies (Abbott, Siemens, Roche) in the country where the sales destination is located, compare and correct the shortcomings of the products, and create high-quality products.

## 2 Material

### 2.1 Patient material

#### 2.1.1 Preparation of the patient

None

#### 2.1.2 Sample material

Nasopharyngeal smear

#### 2.1.3 Sample container

Sterile swab in transport tubes

#### 2.1.4 Storage conditions

- Fresh swab samples (<24h)
- Deep frozen swabs at -80°C. Samples prepared in NaCl (0,9 %).

#### 2.1.5 Sample preparation

To perform the test, all smears already confirmed by PCR are extracted in 200 µl NaCl solution (0.9%). Then 4 fresh swabs from the 4 manufacturers are added to the NaCl solution and incubated together for 15 minutes. Then the rapid test is prepared according to the test instructions.

### 2.2 Test strips

- Amazing Biotech: Covid-19 Antigen Sealing Tube Test Strip (Colloidal Gold)  
 Lot number: G21072001/ 20.07.2021  
 Expiry date: 19.01.2023  
 Ref number: AB00106



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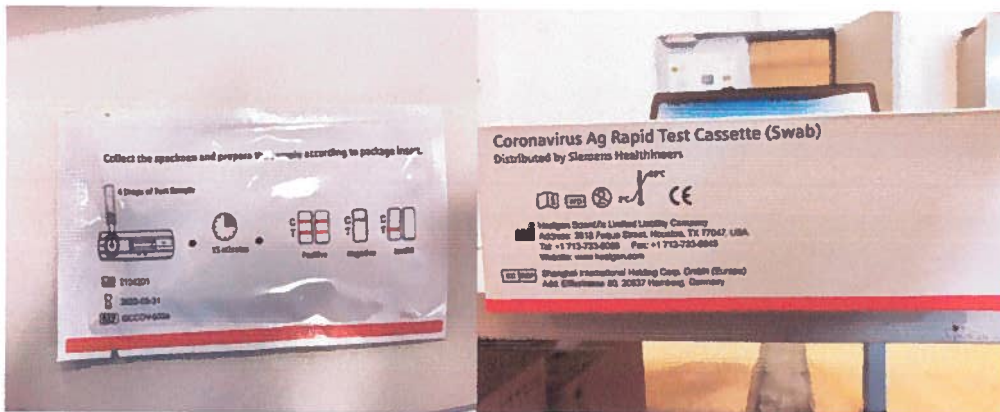
**Comparison study for COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold)**


Doku-Nr.:	VA-500	Version:	1	Seite:	4/14
-----------	--------	----------	---	--------	------

- Reference rapid test 1: **Abbott COVID-19 Ag Rapid Test Device**  
 Lot number: 41ADG186A/ 17.02.2021  
 Expiry date: 16.02.2022  
 Ref number: 41FK11



- Reference rapid test 2: **Siemens Healthineers CLINITEST Rapid COVID-19 Antigen Test**  
 Lot number: 2104201  
 Expiry date: 31.03.2023  
 Ref number: GCCOV-502a



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	<b>SOP</b> <b>Comparison study for COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold)</b>				
	Doku-Nr.:	VA-500	Version:	1	Seite:

- Reference rapid test 3: Roche (SD Biosensor) SARS-CoV-2 Rapid Antigen Test  
 Lot number: QCO391063I/ 20.01.2021  
 Expiry date: 19.01.2023  
 Ref number: 9901-NCOV-01G



### 3 Responsibilities

Laboratory management, Quality management, Technical staff

### 4 Workflow

#### 4.1 False negative rate of positive samples

Types of experimental samples: 75 cases of nasal secretion, which tested positive by rt-PCR. The swab samples were eluted with NaCl solution (0,9%). The parallel control experiment was carried out with the diluent of each manufacturer's product.

##### 4.1.1 Experimental operation

Use the Amazing Covid-19 Antigen Sealing Tube Test Strip (Colloidal Gold) and 3 comparison manufacturers' kits for sample detection experiments at the same time.

#### 4.2 False positive rate of negative samples

Types of experimental samples: 20 cases of nasal secretion. The swab samples were eluted with NaCl. The parallel control experiment was carried out with the diluent of each manufacturer's product.

##### 4.2.1 Experimental operation

Use the Amazing Covid-19 Antigen Sealing Tube Test Strip (Colloidal Gold) and 3 comparison manufacturers' kits for sample detection experiments at the same time.

#### 4.3 Persistence of signal interpretation (Signal stability)

##### 4.3.1 Purpose

To compare the effective time of kits from different manufacturers.


##### 4.3.2 Experimental materials

3 cases of nasal secretion with (weak) positive values. The swab samples were eluted with NaCl. The parallel control experiment was carried out with the diluent of each manufacturer's products.

##### 4.3.3 Experimental method

Take the Amazing Covid-19 Antigen Sealing Tube Test Strip (Colloidal Gold) and the kits from 3 comparison manufacturers, and use the patient samples to test three times for detection. Read the



<b>MVZ Labor Dr. Quade und Kollegen</b>					
	<b>SOP</b>				
	<b>Comparison study for COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold)</b>				
Doku-Nr.:	VA-500	Version:	1	Seite:	6/14

judgment results according to different color development times to confirm the signal stability.

#### **4.4 Convenience of operation**

##### **4.4.1 Purpose**

To compare the time required to complete 10 tests for the same person with kits from different manufacturers.

##### **4.4.2 Experimental materials**

Prepare 40 control samples of the same person. The parallel control experiment was carried out with the diluent of each manufacturer's products. The same positive sample was used for parallel control, 10 times for each test.

##### **4.4.3 Experimental method**

Do all the preparations required for the experiment, take the Amazing kit and the kits of the 3 comparison manufacturers, and record the time required for testing 10 samples. Respectively from the first sample to start sampling and testing start timing, to the completion of the 10th sample testing and sample addition to finish timing. Record the time required for the operation of the 4 products.

#### **4.5 Evaluation of the difference in the amount of sample loaded on the reagent strip**

##### **4.5.1 Purpose**

To compare the instability of the sampled volume of the Amazing product with that of the reference kit.

##### **4.5.2 Experimental materials**

Weak positive threshold samples/quality control products.

##### **4.5.3 Experimental method**

Take the Amazing Covid-19 Antigen Sealing Tube Test Strip (Colloidal Gold) and the 3 comparison manufacturers' kits to detect weak positive threshold samples/quality control products. The reference reagent was added with 2 drops, 3 drops, 4 drops, and multiple drops at a time. Repeat 3 times to determine the result.

#### **4.6 Evaluation of positive sample signal and sensitivity**

##### **4.6.1 Purpose**

To compare and evaluate the sensitivity of different manufacturers' kits to detect positive samples.

##### **4.6.2 Experimental material**

Dilute with a high concentration of positive sample that has been calibrated, The parallel control experiment was carried out with the diluent of each manufacturer's products.

##### **4.6.3 Experimental method**

Take the Amazing Covid-19 Antigen Sealing Tube Test Strip (Colloidal Gold) and the kit of three comparative manufacturers to test the diluted high concentration positive samples. According to the results, the detection status and signal differences of positive samples are counted.

#### **4.7 Leakage safety of the sample**

In order to assess the leakage safety of the sample after the preparation with the Covid-19 Antigen Sealing Tube Test ((Amazing Covid-19 Antigen Sealing Tube Test Strip (Colloidal Gold))) and thus the risk of contamination, the following test procedure was carried out.

##### **4.7.1 Experimental operation**

3 already prepared high positive patient tests ((Amazing Covid-19 Antigen Sealing Tube Test Strip (Colloidal Gold))) were placed in a 50 ml secondary tube (Falcon tube) and rotated on a roller shaker for 3



SOP

Comparison study for COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold)

Doku-Nr.: VA-500 Version: 1 Seite: 7/14

days. After 3 days, the patient test tubes were removed. The secondary tube was then centrifuged to settle any liquid droplets that may have escaped. The contents were then collected with 200 µl NaCl and tested for Covid 19 by rt-PCR.

**4.8 Test signal of inactive virus**

This experiment is intended to show whether the detection of Covid-19 Antigen with the Amazing Covid-19 Antigen Sealing Tube Test Strip (Colloidal Gold) still work after heat inactivation of the sample material.

**4.8.1 Experimental operation**

One patient tested highly positive with rt-PCR (nasal swab) is extracted in the sample buffer of Amazing Covid-19 Antigen Sealing Tube Test Strip (Colloidal Gold) test. After the extraction, the swab is removed. The sample buffer is transferred to an Eppendorf tube with a pipette and then incubated for 15 minutes at 96 °C in a heating block in order to inactivate the corona virus. The buffer is then transferred back into the test tube and the test is carried out according to the instructions.

**5 Documentation**

**5.1 Statistical evaluation**

Negative means "-"  
 weak positive means "(+) or +"  
 medium positive means "++"  
 strong positive means "+++"

**5.2 Comparison index**

**5.2.1 Comparison of the results of 75 positive samples (nasal secretions) tested by 4 products**

Position	Labornummer	PCR	Abbott	Roche	Siemens	Amazing	Variante
1	0200203286	positive	-	(+)	(+/-)	(+)	Delta
2	0900328411	positive	+++	+++	+++	+++	Delta
3	0900322860	positive	++	+++	+++	+++	na
4	0900328297	positive	+++	+++	+++	+++	Delta
5	0900318483	positive	+	++	+++	+++	Delta
6	0011157128	positive	+++	+++	+++	+++	Delta
7	0001361925	positive	+++	++	+++	+++	Delta
8	0003278545	positive	+++	+++	+++	+++	Delta
9	0010782322	positive	-	-	-	++	na
10	0011205845	positive	++	+	-	+	Delta
11	0011179260	positive	-	+	+	+++	na
12	0011179348	positive	+++	+++	+++	+++	Delta
13	0011201631	positive	+++	+++	+++	+++	Delta
14	0034037151	positive	+	+	+	-	Delta
15	0011197793	positive	-	-	+	+	Delta
16	0030574547	positive	-	+	-	++	Delta
17	0011180822	positive	+	+++	++	+++	Alpha
18	0200204077	positive	-	++	+	++	Delta
19	0003815675	positive	+++	+++	+++	+++	na

MVZ Labor Dr. Quade und Kollegen



SOP

Comparison study for COVID-19 Antigen Sealing Tube Test Strip  
(Colloidal Gold)

Doku-Nr.: VA-500      Version: 1      Seite: 8/14

Position	Labornummer	PCR	Abbott	Roche	Siemens	Amazing	Variante
20	0900328346	positive	+++	+++	+++	+++	Delta
21	0011234941	positive	+++	+++	+++	+++	na
22	0011233262	positive	++	+++	+++	++	na
23	0200204436	positive	+++	+++	+++	+++	na
24	0034037353	positive	+	++	+++	+++	Delta
25	0011235016	positive	+++	+++	+++	+++	na
26	0036150338	positive	+	+++	+++	++	Delta
27	0011177760	positive	+++	++	+++	+++	na
28	0000554962	positive	+	+++	+++	+++	Delta
29	0200203288	positive	+++	+++	++	+++	Delta
30	0034036960	positive	(+)	+++	+++	+++	Delta
31	0034037358	positive	+	++	+++	++	Delta
32	0900328377	positive	+++	+++	+++	+++	Delta
33	0900328356	positive	+++	+++	+++	+++	Delta
34	0900328374	positive	+++	+++	+++	+++	Delta
35	0011218939	positive	+	+	+	+	Delta
36	0011199331	positive	+++	+++	+++	+++	Delta
37	0034037196	positive	+++	+++	+++	+++	Delta
38	0000554967	positive	+	+	+	+++	Delta
39	0036150276	positive	+	+	+	+	Delta
40	0900330753	positive	+++	+++	+++	+++	na
41	0036058291	positive	+++	+++	+++	+++	Delta
42	0003278544	positive	-	+	+	+	Delta
43	0036057903	positive	-	-	+	+	Delta
44	0011200058	positive	+++	+++	+++	+++	Delta
45	0011234263	positive	+++	+++	+++	+++	na
46	0000554898	positive	+++	+++	+++	+++	Delta
47	0011236348	positive	+	+	++	++	Delta
48	0030574675	positive	+++	+++	+++	+++	Delta
49	0001361594	positive	+++	+++	+++	+++	Delta
50	0003263685	positive	+++	+++	+++	+++	Delta
51	0030574635	positive	+++	+++	+++	+++	Delta
52	0034036979	positive	+	++	++	+++	Delta
53	0011199356	positive	+++	+++	+++	+++	Delta
54	0200204078	positive	-	-	+	+	Delta
55	0900288148	positive	-	-	-	++	Delta
56	0011199284	positive	+++	+++	+++	+++	Delta
57	0034037203	positive	-	-	-	-	Delta
58	0011219852	positive	+++	+++	+++	+++	na



**MVZ Labor Dr. Quade und Kollegen**



**SOP**

**Comparison study for COVID-19 Antigen Sealing Tube Test Strip  
(Colloidal Gold)**

Doku-Nr.: VA-500      Version: 1      Seite: 9/14

Position	Labornummer	PCR	Abbott	Roche	Siemens	Amazing	Variante
59	0036057171	positive	-	+	+	++	Delta
60	0036055806	positive	-	-	-	-	Delta
61	0036057875	positive	-	-	-	+	Delta
62	0036058504	positive	-	+	-	++	Delta
63	0001619470	positive	-	-	-	-	Delta
64	0900270948	positive	+	+	+	+	Delta
65	0011206552	positive	+++	+++	+++	+++	Delta
66	0011201305	positive	+++	+++	+	+++	Delta
67	0011217760	positive	+	-	+	+	Delta
68	0011205093	positive	+++	++	+++	+++	Delta
69	0900270949	positive	+	+	-	-	Delta
70	0040073119	positive	-	-	-	-	Delta
71	0036150337	positive	++	++	++	+++	Delta
72	0034037230	positive	+	+	+	+	Delta
73	0011236050	positive	++	+	+++	++	Delta
74	0034037446	positive	+	+	+	+	Delta
75	0034037327	positive	-	+	+	-	Delta

5.2.2 Statistics of experimental results: Comparison table of false negative rates of test samples for four products

Product Name	Nasal secretions 75 cases	
	Number of negative cases	Number of positive cases
Amazing reagent	7	68
Abbott	18	57
Siemens Healthineers	11	64
Roche (SD Biosensor)	11	64
PCR	0	75

5.2.3 Example picture of positive test results





**SOP**

**Comparison study for COVID-19 Antigen Sealing Tube Test Strip  
(Colloidal Gold)**


Doku-Nr.: VA-500      Version: 1      Seite: 10/14

**5.2.4 Comparison of the results of 20 negative samples (nasal secretions) tested by 4 products**

		<b>Abbott</b>	<b>Roche</b>	<b>Siemens</b>	<b>Amazing</b>	<b>PCR</b>
1	001267983	-	-	-	-	-
2	0011267298	-	-	-	-	-
3	0200205110	-	-	-	-	-
4	0030574887	-	-	-	-	-
5	0030574816	-	-	-	-	-
6	0030574823	-	-	-	-	-
7	0030574823	-	-	-	-	-
8	0030574885	-	-	-	-	-
9	0011265466	-	-	-	-	-
10	0011267425	-	-	-	-	-
11	0011265560	-	-	-	-	-
12	0011263568	-	-	-	-	-
13	0011263568	-	-	-	-	-
14	0011261884	-	-	-	-	-
15	0200205108	-	-	-	-	-
16	0200205109	-	-	-	-	-
17	0011264683	-	-	-	-	-
18	0011261489	-	-	-	-	-
19	0011266137	-	-	-	-	-
20	0011267269	-	-	-	-	-

**5.2.5 Statistics of experimental results: Comparison table of false positive rates of test samples for four products**

Product Name	Nasal secretions 20 cases	
	Number of negative cases	Number of positive cases
Amazing reagent	20	0
Abbott	20	0
Siemens Healthineers	20	0
Roche (SD Biosensor)	20	0
PCR	20	0

<b>MVZ Labor Dr. Quade und Kollegen</b>					
	<b>SOP</b>				
	<b>Comparison study for COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold)</b>				
Doku-Nr.:	VA-500	Version:	1	Seite:	11/14

5.2.6 Example picture of negative test results



5.3 Persistence of signal interpretation (Signal stability)

5.3.1 Interpretation table of response time persistence results for four product kits.

Reaction time	Amazing reagent			Abbott			Siemens Healthineers			Roche (SD Biosensor)		
	1 CT: 19.6	2 CT: 21.8	3 CT: 18.0	1 CT: 19.6	2 CT: 21.8	3 CT: 18.0	1 CT: 19.6	2 CT: 21.8	3 CT: 18.0	1 CT: 19.6	2 CT: 21.8	3 CT: 18.0
15 min (27.08.21)	+++	+++	+++	+	+	+	+++	+++	++	+++	++	+++
30 min (27.08.21)	+++	+++	+++	+	+	+	+++	+++	++	+++	++	+++
60 min (27.08.21)	+++	+++	+++	+	+	+	+++	+++	++	+++	++	+++
24 hours (28.08.21)	+++	+++	+++	+	(+)	(+)	+++	+++	++	+++	++	+++
3 days (30.08.21)	+++	+++	+++	+	(+)	(+)	+++	+++	++	+++	+	+++
10 days (06.09.21)	+++	+++	+++	+	(+)	(+)	+++	+++	++	+++	+	+++

## 5.4 Convenience of operation

### 5.4.1 Comparison of the time required to complete 10 samples of the four products

Product name	Sample completion time of 10 samples (seconds)
Amazing reagent	1062 (17,7 Minuten)
Abbott	1488 (24,8 Minuten)
Siemens Healthineers	1638 (27,3 Minuten)
Roche (SD Biosensor)	1350 (22,5 Minuten)

### 5.4.2 Ease of use

- Covid-19 Antigen Sealing Tube Test Strip (Colloidal Gold)  
Benefits: leak-proof, low risk of contamination, easy to use, easy to interpret  
Disadvantages: Aluminium foil must be opened completely, otherwise the buffer will not run into the cap when the tube is turned over.



- Reference rapid test 1: Abbott COVID-19 Ag Rapid Test Device  
Benefits: easy to interpret  
Disadvantages: cumbersome use, dropper does not work properly every time it is used, Buffer must be supplied by the user, risk of contamination
- Reference rapid test 2: Siemens Healthineers CLINITEST Rapid COVID-19 Antigen Test  
Benefits: easy to interpret  
Disadvantages: Buffer must be supplied by the user, risk of contamination
- Reference rapid test 3: Roche (SD Biosensor) SARS-CoV-2 Rapid Antigen Test  
Benefits: easy to interpret, easy to use  
Disadvantages: risk of contamination

## 5.5 Evaluation of the difference in the amount of sample loaded on the reagent strip

### 5.5.1 Repeatability result judgment

Product name	Sample volume	Result one	Result two	Result three
Amazing reagent (100 µl)	N-2	+++	+++	+++
	N-1	+++	+++	+++
	N	+++	+++	+++





SOP

Comparison study for COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold)


Doku-Nr.: VA-500      Version: 1      Seite: 13/14

	N+1	+++	+++	+++
	N+2	+++	+++	+++
Abbott (N= 5 drops)	N -2 drops	+++	+++	+++
	N -1 drop	+++	+++	+++
	N	+++	+++	+++
	N +1 drop	+++	+++	+++
	N+2	+++	+++	+++
Product name	Sample volume	Result one	Result two	Result three
Siemens Healthineers (N=4 drops)	N -2 drops	+++	+++	+++
	N -1 drop	+++	+++	+++
	N	+++	+++	+++
	N +1 drop	+++	+++	+++
	N +2 drops	+++	+++	+++
Roche (SD Biosensor) (N=3 drops)	N -2 drops	invalid	invalid	Invalid
	N -1 drop	+++	+++	+++
	N	+++	+++	+++
	N +1 drop	+++	+++	+++
	N +2 drops	+++	+++	+++

## 5.6 Evaluation of positive sample signal and sensitivity

### 5.6.1 Comparison of test results of 4 products (Ct=16,6)

Sample dilution ratio	Amazing reagent	Abbott	Siemens Healthineers	Roche (SD Biosensor)
1) Nativ	+++	+++	+++	+++
2) 1:2	+++	+	+++	++
3) 1:4	++	+	++	++
4) 1:8	+	-	+	+
5) 1:16	+	-	-	+
6) 1:32	-	-	-	-
7) 1:64	-	-	-	-

<b>MVZ Labor Dr. Quade und Kollegen</b>					
	<b>SOP</b>				
	<b>Comparsion study for COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold)</b>				
	Doku-Nr.:	VA-500	Version:	1	Seite:

## 6 Final conclusion

The COVID-19 Ag Sealing tube test strip (Colloidal Gold) from Amazing Biotech proved to be a user-friendly and safe test in our comparative study. The test is very easy to perform compared to competitor products and does not require any additional steps to prepare the test. With the 3 comparison products from Siemens, Roche and Abbott, the smear is extracted in separate test tubes and the buffer has to be added in some cases (Abbott, Siemens). These additional steps are not necessary with the Amazing Biotech test because the smear is extracted directly in the test tube. In addition, there is no need for dripping onto the test strip, because this is directly integrated in the Amazing Biotech Test. These unnecessary additional steps reduce the risk of using the test incorrectly. After the test has been carried out, the lid is closed absolutely tightly by the safety lock, so that no contamination with infectious material can occur. The interpretation of the test result is clear and easy to read. Even after several days, the intensity of the bands remains and the result can still be clearly interpreted.

## 7 Modification service

The quality unit is responsible for changes to these procedural instructions. The changes are reviewed by the quality unit and the medical director. The medical management approves the change.

## 8 Supplied documents

### 8.1.1 Manufacturer's test instructions

- COVID-19 Ag RAPID Test Device (nasal), Abbott, 2020
- Clinitest Rapid COVID-19 Antigen Test, Siemens Healthineers, 2020
- SARS-CoV-2 Rapid Antigen Test, Roche (SD Biosensor), 12/2020, Vers. 2
- Amazing Biotech: Covid-19 Antigen Sealing Tube Test Strip (Colloidal Gold)