DRK-Blutspendedienst
Baden-Württemberg | Hessen
gemeinnützige GmbH

Deutsches
Rotes
Kreuz

Comparison of three SARS Antigen Rapid Assays

Prof. Dr. M. Schmidt
Prof. Dr. E. Seifried

Analytical Sensitivity

- Roche SD BIOSENSOR SARS-CoV-2 Rapid Antigen Test
- Abbott Panbio™ COVID-19 Ag Rapid Test Device
- PCL COVID19 Ag Gold
- Dilution series of SARS Standard; quantitated with GFE SARS-CoV-2 PCR Kit, PCR Threshold Cycle (Ct) Ct 18 - Ct 22
- Triplicate determination of each dilution level in each Rapid Assay

Dilution level no.	Ct value	Roche	Abbott	PCL
Level 4	18	3x	3x	3x
Level 5	19	3x	3x	3x
Level 6	20	3x	3x	3x
Level 7	21	3x	3x	3x
Level 8	22	3x	3x	3x

Results dilution level 4 – Ct 18

Abbott Roche PCL

ST4 = dilution level 4

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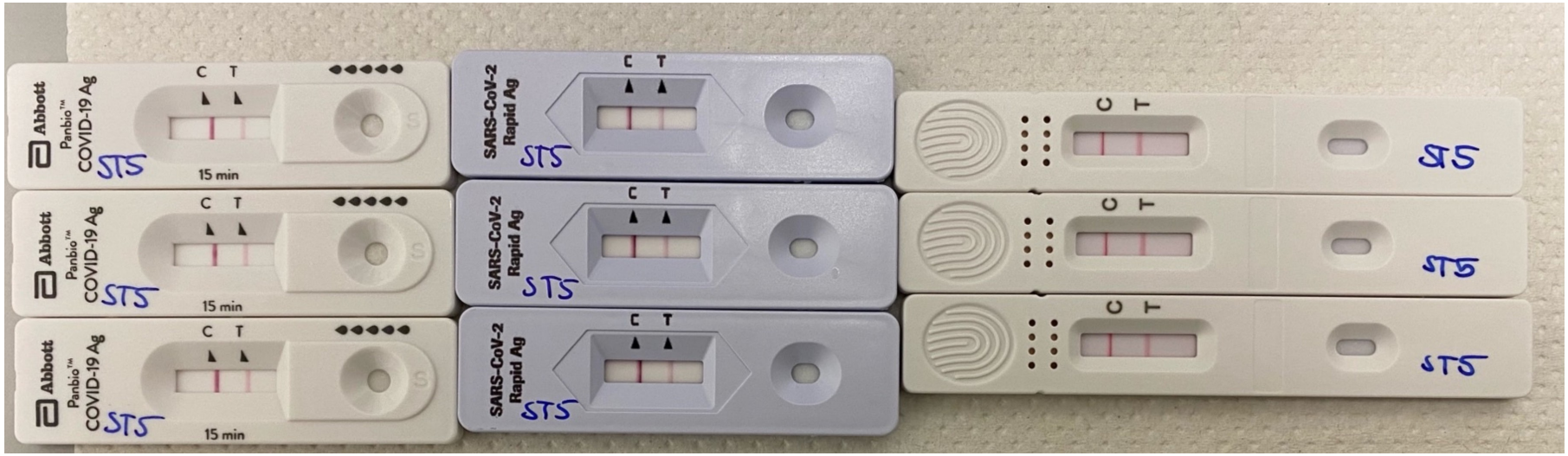
Results dilution level 5 – Ct 19

Abbott Roche PCL



ST5 = dilution level 5

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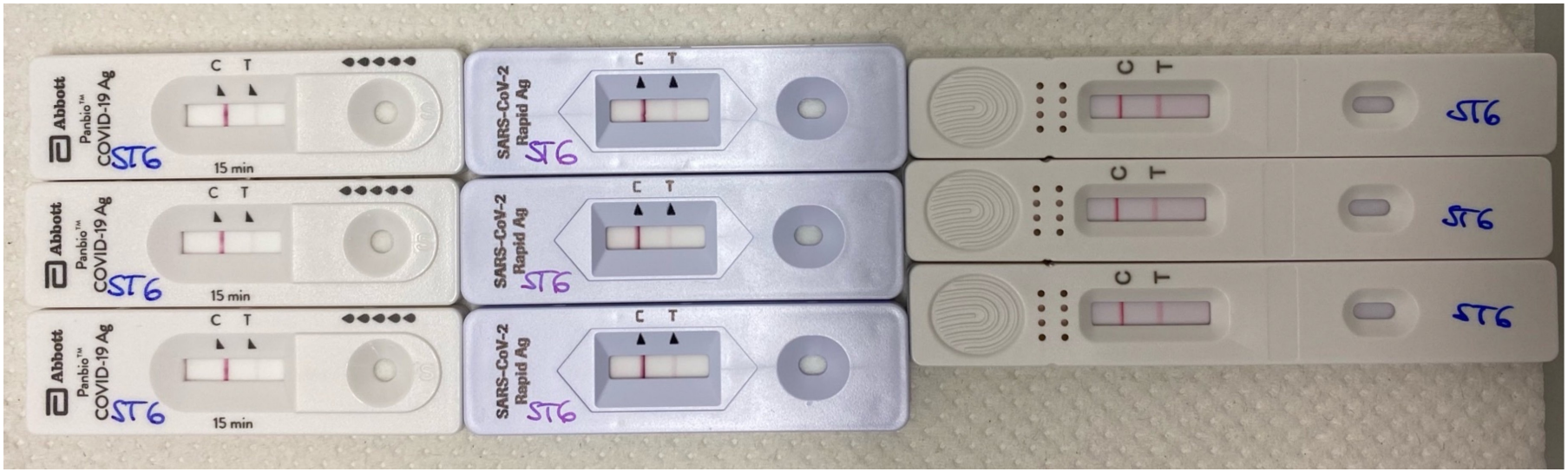
Results dilution level 6 – Ct 20

Abbott Roche PCL



ST6 = dilution level 6

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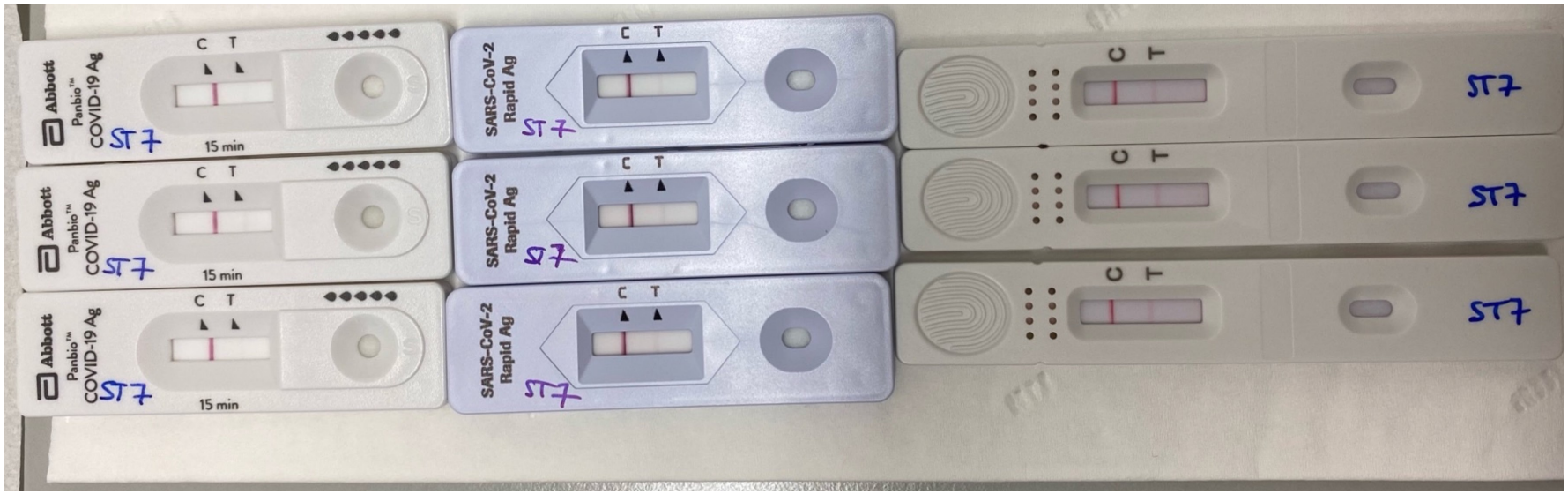
Results dilution level 7 – Ct 21

Abbott Roche PCL



ST7 = dilution level 7

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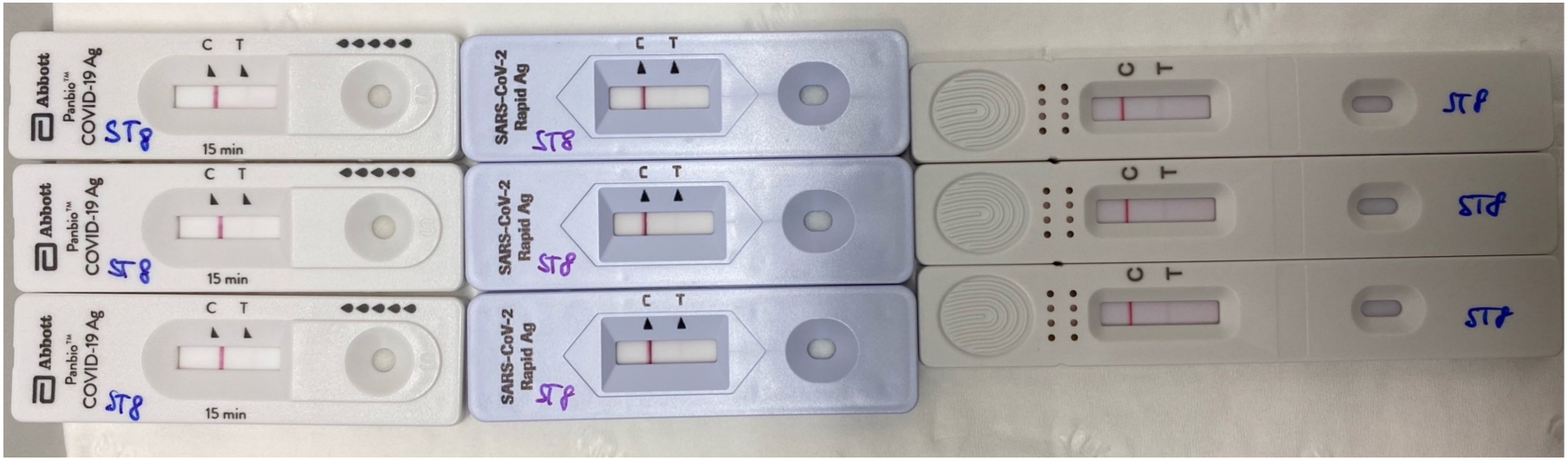
Results dilution level 8 – Ct 22

Abbott Roche PCL



ST8 = dilution level 8

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Results Analytical Sensitivity

Dilution level no.	Ct value	Roche	Abbott	PCL
Level 4	18	3/3	3/3	3/3
Level 5	19	3/3	3/3	3/3
Level 6	20	3/3	3/3	3/3
Level 7	21	3/3	3/3	3/3
Level 8	22	0/3	0/3	3/3

- Roche SARS-CoV-2 (Ct 21)
- Abbott SARS-CoV-2 (Ct 21)
- PCL SARS-CoV-2 (Ct 22)

Diagnostic Specificity, swab samples

- 200 samples each tested negative in GFE SARS-CoV-2 PCR were tested in the rapid assays

	POS	NEG
Roche rapid assay	3	197
Abbott rapid assay	1	199
PCL rapid assay	0	200

	Specificity
Roche rapid assay	98.5 %
Abbott rapid assay	99.5 %
PCL rapid assay	100 %

Diagnostic Sensitivity, swab samples

- Three series of 200 samples out of routine testing were initially tested in a rapid assay and subsequently in GFE SARS-CoV-2 PCR

	POS	NEG
Roche rapid assay	4	196
GFE PCR	6	194

	POS	NEG
Abbott rapid assay	5	195
GFE PCR	6	194

	POS	NEG
PCL rapid assay	6	194
GFE PCR	8	192

- Rapid assay positive samples had Ct ≤ 20

Reassessment of COVID routine diagnostic samples

- Period 1: June to September 2020
- Period 2: September to December 2020

Period 1: June to September 2020

Total samples	Ct ≤ 21	Ct > 21
1083	210	873

Total samples	Ct ≤ 22	Ct > 22
1083	263	820

- Abbott / Roche: Estimated Sensitivity 19.4 %
- PCL: Estimated Sensitivity 24.3 % (or higher[1])

[1] *The dilution series used to determine the analytical sensitivity does not include the endpoint for the PCL rapid assay. Therefore the Ct value corresponding to the highest dilution level (level 8, Ct 22) was used for the reassessment.*

Period 2: September to December 2020

Total samples	Ct ≤ 21	Ct > 21
552	289	263

Total samples	Ct ≤ 22	Ct > 22
552	310	242

- Abbott / Roche: Estimated Sensitivity 52.4 %
- PCL: Estimated Sensitivity 56.2 % (or higher[1])

[1] *The dilution series used to determine the analytical sensitivity does not include the endpoint for the PCL rapid assay. Therefore the Ct value corresponding to the highest dilution level (level 8, Ct 22) was used for the reassessment.*

Summary

- Analytical Sensitivity of PCL COVID Assay superior to Roche & Abbott
- Diagnostic Sensitivity comparable in 200 samples from routine
- Amount of positive tested samples correlates with incidence
- Rapid assays are very suitable in environments with symptomatic individuals