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The DOI for this manuscript is doi: 10.5858/arpa.2020-0499-SA

The final published version of this manuscript will replace the Early Online Release version at the above DOI once it is available.
Comparative Clinical Evaluation of the Roche Elecsys and Abbott SARS-CoV-2 Serology assays for COVID-19

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Running Title: Comparison of two SARS-CoV-2 assays

Dr Tambyah has received grants paid to the National University Hospital from Roche (CP40617, MV40618), Johnson & Johnson (63623872FLZ3001, 63623872FLZ2002), Sanofi Pasteur (H-030-014), GlaxoSmithKline, and Shionogi (1601T0831). The other authors have no relevant financial interest in the products or companies described in this article.
Abstract

**Context:** The use of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) serological tests detect antibodies in the host, contributing to the identification of individuals who have been exposed to Coronavirus Disease 2019 (COVID-19).

**Objective:** To critically evaluate two commercially available SARS-CoV-2 serology tests.

**Design:** A total of 333 unique, non-duplicated serum samples obtained from COVID-19 patients (n=170) and negative controls (n=163) obtained pre-December 2019 were used in the study. Samples were tested on the Roche E411 and Abbott Architect i4000SR platforms and results were correlated to reverse transcription polymerase chain reaction (PCR) results and clinical symptoms.

**Results:** There was a strong level of agreement in the qualitative results between both assays with a Cohen’s kappa value of 0.840, *P*<.001. The specificity for both Roche and Abbott were excellent at 100%. Roche exhibited marginally better performance in the ≥21 days group with a sensitivity of 90.6% (95% CI 75.8-96.8%) versus Abbott’s sensitivity 84.4% (95% CI 68.3 – 93.1%) as well as the 14-20 days group with a sensitivity of 85.7% (95% CI 65.4 – 95.0%) versus Abbott sensitivity 81.0% (95% CI 60.0 – 92.3%). Less than 14 days of symptoms groups exhibited poor sensitivity at <50% for both assays. The area under curve (AUC ± standard error) for Roche (0.894 ± 0.025, *P*<.001) and Abbott (0.884 ± 0.026, *P*<.001) were very similar. Potential confounders for negative serological results include anti-retroviral medication use and pauci-symptomatic patients.

**Conclusions:** Specificities for high throughput Roche and Abbott immunoassays are excellent but users need to be cautious to interpret serological test results after 14 days of symptoms to avoid false negatives.
INTRODUCTION

Coronavirus Disease 2019 (COVID-19) has now been declared a public health pandemic by the World Health Organization (WHO) since its initial outbreak in Wuhan, China. COVID-19 patients may present with non-specific symptoms ranging from mild respiratory tract illness to severe pneumonia requiring intensive care support hence posing diagnostic difficulties to clinician. The gold-standard laboratory diagnosis of COVID-19 relies on detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) nucleic acid by real-time reverse transcription polymerase chain reaction (RT-PCR) based on gene targets such as N, E, RdRp, orf1a and orf1b genes. PCR-based molecular testing turnaround time varies from a few hours to days taking into consideration the expertise of the laboratory in question, as well as workload, type and throughput of analyzers in operation. Coupled with limited RT-PCR reagent/kit availability, there have been some initiatives to utilize SARS-CoV-2 serology as a screening test or for surveillance of within a population. Serological tests detect antibodies in the host as immunoglobulin G (IgG), immunoglobulin M (IgM) and/or immunoglobulin A (IgA) to SARS-CoV-2, contributing to the identification of individuals who have been exposed to COVID-19, possibly obtaining immunity and further assist in containment or isolation strategies or even the idea of “immune passports”. Zhao and colleagues have recently shown that the median seroconversion time for IgM and IgG was 11 days and 12 days respectively and that specific IgG antibodies to SARS-CoV-2 remain detectable in COVID-19 patients during the symptomatic phase of the disease even after ribonucleic acid (RNA) becomes undetectable. A plethora of serology kits have now entered the market, often with claims of good performance, many also having obtained provisional FDA approval or CE marking. In this study, we sought to compare the diagnostic accuracy of two commercially available, automation-track compatible SARS-CoV-2 serology assays, namely the Roche Elecsys and Abbott Architect Anti-SARS-CoV-2 assays. Chew et
al and Tang et al had previously shown that Abbott performed reasonably well with a duration of 14 days being suggested as a minimum period to test symptomatic COVID-19 patients for the presence of antibodies. As the COVID-19 situation is rapidly evolving, there is a need to inform laboratory users of potential differences in the interpretation of SARS-CoV-2 serology assays.

**METHODS**

A total of 333 unique, non-duplicated serum samples obtained from COVID-19 confirmed patients (n=170) and negative controls (n=163) obtained pre-December 2019 before the COVID-19 pandemic were used in the study. We prospectively selected samples between 30th of March 2020 to 15th of May 2020 from COVID-19 patients in our institution on the basis of at least one positive RT-PCR respiratory sample being positive on our cobas 6800 SARS-CoV-2 assay (Roche Diagnostics, Rotkreuz, Switzerland), with the cycle threshold (CT) value being lower than cut-off. Samples were collected in serum separator tubes (Beckton Dickinson, New Jersey, USA), centrifuged at 3000 rpm for 8 minutes and after clinical testing, residual sera were collected in accordance with previously described laboratory protocols for COVID-19 sample handling. These serum samples were then concurrently analyzed on the cobas e411 (Roche Diagnostics, Rotkreuz, Switzerland) and Abbott Architect i4000SR (Abbott Diagnostics, Chicago, USA) analyzer using their respective assays. Days of symptoms were recorded based on first day of onset of COVID-19 symptoms as recorded by managing clinicians to the time of blood collection. Patients who were asymptomatic at the time of PCR testing were excluded. A repository of archived negative controls were utilized with samples taken from patients prior to December 2019. These include patients with and without other positive serological tests which exhibit the following: anti-extractable nuclear antigen antibodies (9); anti-glomerular basement
membrane antibodies (4); anti-smooth muscle antibody (3); Epstein-barr virus IgM (3); anti-intrinsic factor (5); Cytomegalovirus IgM (4); Cytomegalovirus IgG (3); Syphilis Treponema Pallidum antibody (5); Hepatitis B E Antigen (2); Epstein-Barr virus IgA (7); Leptospira IgM (3); Hepatitis C (9); Hepatitis B surface antigen (7); anti-double strand DNA (3); Rubella IgM (4); ANA (3); Hepatitis A IgG (3); Dengue IgG (1); Varicella zoster IgG (6). In brief, both are chemiluminescent immunoassays detecting antibodies to the nucleocapsid protein of SARS-CoV-2 producing a qualitative result (reactive vs non-reactive) but with a quantitative signal cut-off index value. The key difference between both assays is that Abbott detects only immunoglobulin G (IgG) antibodies, whereas the Roche detects total antibodies (both IgM and IgG) to SARS-CoV-2. Prior to analyses on patients’ sera, calibration was performed and quality controls were passed as per manufacturers’ instructions. A signal cutoff index (S/C) ratio of ≥1.4 was interpreted as reactive and a S/C ratio of <1.4 was interpreted as non-reactive for the Abbot assay; and a signal cutoff index (COI) of ≥1.0 was interpreted as reactive and a COI of <1.0 was interpreted as non-reactive for the Roche assay in accordance to manufacturers’ product insert.

Statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) 25.0 with statistical significance set at $P < .05$. The relationship between the two immunoassays and their qualitative agreement were assessed using Pearson’s correlation and Cohen’s kappa, respectively. A one-way analysis of variance (ANOVA) was conducted to compare the mean levels of SARS-CoV-2 antibody signals with Tukey Honest significant difference (HSD) corrections for Post-hoc comparisons. Chi-square test was performed to compare the sensitivities of both assays on a Reactive-signal and Area under the curve (AUC) presented to compare the diagnostic capabilities of both assays. Our study was approved by
the National Healthcare Group Domain Specific Review Board (Singapore, NHG ROAM Reference Number: 2020/00337 and 2020/00407).

RESULTS

Correlation Between Roche and Abbott

We compared the quantitative signal output of the Roche and Abbott where Figure 1 showed a moderate Pearson’s correlation coefficient of 0.734 ($P<.001$) between both assays. Signal intensities were in general greater in the Roche assay which is not unexpected because it is a total antibody assay as compared to the Abbott assay. Figure 2 depicts the Bland-Altman plot showing the positive bias in the Roche assay. Sixty-nine out of 170 (40.6%) confirmed COVID-19 cases were reactive for the Roche assay whilst 66 out of 170 (38.8%) were positive in the Abbott assay. There was a strong level of agreement in the qualitative results between both assays with a Cohen’s kappa value of 0.840, $P< .001$, (Table 1).  

Signal/Cut-Off Values

Next we proceeded to look at the quantitative signal cut off values generated for each assay which showed that peak signals in both assays were generated between 10 to 15 days and troughed by 45 days although signals remained detectable. The Roche assay also showed greater signal values generated across all levels as compared to the Abbott assay, demonstrated in the scatter-plot in Figures 3A, 3B. We stratified the positive COVID-19 patients into 4 groups: ≥21 days of symptoms (n = 32), 14-20 days of symptoms (n = 21), ≥7 - 13 days of symptoms (n = 37) and <7 days of symptoms (n = 80). The mean signal cutoffs are presented in table 2 and 3 and their respective histograms in Figures 4A, 4B. A one-way
analysis of variance (ANOVA) showed a significant difference across the different days of symptoms for the Roche \[F(3,166) = 55.5, P<.001\] and the Abbott \[F(3,166) = 38.9, P<.001\]. We had previously shown that a post-hoc comparisons using the Tukey HSD test indicated that there was a significant difference \(P< .001\) in mean S/CO IgG levels in the Abbott assay for patients with 7-13 days versus 14-20 days of symptom suggesting that IgG antibodies peaked at the latter period.\(^6\) Fourteen to twenty days also produced the greatest mean signal intensities for Abbott IgG titres. Interestingly in the Roche data we saw that the “total antibody” assay detects the greatest mean signal intensities in the >21 day group (mean 44.18 COI) which was significantly greater than in the 14-20 day group (mean 13.68 COI) from the post-hoc Tukey HSD test \(P< .001\) indicating that total antibody production in the COVID-19 patients continued well past the 14 day period.

**Diagnostic Accuracy**

The specificity for both Roche and Abbott were excellent at 100\% and demonstrated no cross-reactivity to any of the sero-positive viruses or autoimmune disorders. Table 4 shows the overall sensitivity was 40.6\% (95\% CI 33.5-48.1\%) in Roche and 38.8\% (95\% CI 31.8-46.3\%) in Abbott. Roche exhibited marginally better performance in the ≥21 days group with a sensitivity of 90.6\% (95\% CI 75.8-96.8\%) versus Abbott’s sensitivity 84.4\% (95\% CI 68.3 – 93.1\%) as well as the 14-20 days group with a sensitivity of 85.7\% (95\% CI 65.4 – 95.0\%) versus Abbott sensitivity 81.0\% (95\% CI 60.0 – 92.3\%). Less than 14 days of symptoms groups exhibited poor sensitivity at <50\% for both assays. There were no significant differences in overall sensitivity \(P=.74\) nor between individual subgroups. The area under curve (AUC ± standard error) for Roche \(0.894 ± 0.025, P< .001\) and Abbott \(0.884 ± 0.026, P<.001\) were very similar (Figure 5). This implies that diagnostic sensitivities are
comparable between both assays for assessing seroconversion status of COVID-19 patients after 14 days.

**Negative Serology Cases Who Were Confirmed COVID-19**

We reviewed the cases in the 14-20 days and ≥21 days groups who were negative on serology but were confirmed COVID-19 cases on PCR. In the 14-20 days group, three patients were both negative on Roche and Abbott. Two of whom had only mild acute respiratory illness (ARI) without any evidence of immunocompromise or respiratory distress. However, one had to be intubated, had lymphopenia and lopinavir-ritonavir (Kaletra) was administered but otherwise was not on any other immunosuppressive regimens nor given transfusions. Interestingly, one patient in this group was non-reactive (S/CO 0.62) on the Abbott, but reactive (15.71 COI) on the Roche. This patient had end-stage renal failure secondary to IgA nephropathy, had a previous renal transplant and was on mycophenolate (Myfortic) immunosuppressant but otherwise did not have any intensive care unit (ICU) stay. In the >21 days group, three patients were negative for in both Abbott and Roche assay. Two patients were negative for the Abbott assay (SCO values 1.11 and 1.28) while they were positive on the Roche assay (COI values 3.55 and 1.4 respectively). All these 5 patients in this group were followed-up in the infectious disease clinic and all only had mild ARI symptoms in the beginning without immunocompromise nor required intubation.

**DISCUSSION**

Current data suggests that there is limited utility for serology assays in the diagnosis of acute clinical SARS-Cov-2 infections. Serology testing may be able to detect patients who have been infected, particularly when testing is performed at least fourteen days after onset of
infection. However, this may not be able to differentiate current vs previous infection. COVID-19 serological assays may have utility in seroprevalence studies, contact tracing strategies, screening essential workers and travelers, and may have a role in ascertaining response to potential vaccines. Both assays in our study have demonstrated excellent performance in terms of specificity. No cross-reactivity was observed in the 103 samples of sero-positive viruses or autoimmune disorders nor in the 60 healthy sera collected pre-December 2019. To our knowledge, this is the first study which has critically assessed the diagnostic performance and correlation of two commercially available immunoassays for SARS-CoV-2 antibodies using a broad number of samples from COVID-19 patients and negative controls. Roche and Abbott are leading manufacturers in many clinical chemistry and microbiology laboratories and their respective assays are laboratory automation system compatible. With COVID-19 having been declared by the World Health Organization as a global pandemic¹, such high throughput platforms incorporating relatively fast (<30 minute) assays will likely become a mainstay in most Laboratory Medicine departments.

Our sensitivity data show that Roche marginally out-performs Abbott at critical time points of 14 days and 21 days, although with overlapping 95% confidence intervals. This could be due to the Roche Elecsys assay measuring total antibodies, while the Abbott assay specifically detects IgG. However, there were no significant differences in the earlier time-points and overall sensitivities when incorporating early time-points remain poor. Our data has shown that sensitivities >21 days only reached 90.6% in the Roche assay and 84.4% in the Abbott assay. Interestingly if we inspect the validation data from the Roche insert, they use days post PCR confirmation and described a 100% sensitivity in >14 days for n=29 samples. The use of post PCR days as a criterion by Roche for classifying days of symptoms may lead to a bias in reporting, as the true number of days of symptoms for the patient could
very well be much more than reported. Our Roche data is consistent with that found by Public Health of England which had reported a sensitivity of around 87% for days of symptoms >14 days or >21 days.\textsuperscript{10} The Abbott assay’s product insert also claimed a sensitivity of 100% post 14 days (n = 88 sera). However, our study had more unique patients (n=170); Abbott had only 31 unique patients and Roche had only 69 patients which suggested that the manufacturers had used duplicated patient’s sera for the study. Use of duplicated patients’ samples across their natural history of illness will serve as a better cohort for investigating sero-conversion instead of diagnostic accuracy which was the aim of our study. Having duplicated patients and the use of multiple sera from the same patient across different time points may allow an early seroconversion patient to continue demonstrating presence of antibodies hence skewing the results to falsely elevated sensitivities across groups.

Based on the mean signal intensities, our results suggested that IgG alone peaked earlier than total antibodies (IgM and IgG) and this is in line with results by Long et al’s group who showed that IgG seroconversion occurred earlier than IgM in their subset of patients.\textsuperscript{11} Clinicians have to be cognizant that testing earlier than the 14-days time point could risk a higher likelihood of false negatives as patients may not have had sufficient time to develop antibodies in their immune system. Our findings are further corroborated by the report by Zhao et al, who showed that SARS-CoV-2 IgG takes a minimum of 12 days to show up in COVID-19 patients’ serum.\textsuperscript{4}

It must be appreciated that both assays in this study have antigens directed against the nucleocapsid protein, and as such both results may be sufficiently correlated to a large extent based on their cohen’s kappa score. Users should be aware of the existence of other
commercially available assay configurations directed against different antigens which may include spike protein, receptor binding domain (RBD) protein, as well as viral neutralizing antibody assays. In particular, neutralizing antibodies confer a status of “true immunity” upon the host and they function by inhibiting RBD from binding to their receptors and hence prevent spike protein 2 mediated entry into the host cell. Many vaccine trials are now focusing on the spike protein target for SARS-CoV-2 to elicit an immune response of B and T cells in the host.

We had several limitations in our study. First, we did not have access to sera from patients infected with other human coronaviruses such as SARS-CoV-1 or MERS-CoV which would serve to strengthen our cross-reactivity data. In light of limited reagent availability and the short on-board stability, we also had difficulty in performing imprecision and interference studies which could be presented at a later time. Lastly, in view of limited residual sera and the need to analyze results on both platforms we had fewer n-numbers in the 14-21 days subgroup.

In conclusion, our report shows very good specificity for both Abbott and Roche SARS-CoV-2 antibody assays, although poorer than expected sensitivities compared to the manufacturer’s claims. Some of the potential factors which may influence a negative serology result in a COVID-19 positive patient include that of immunosuppressive regimens or drugs such as lopinavir-ritonavir, as well as mild acute respiratory illness which we postulate could cause the host to mount an insufficient immune response. Lastly, patients who have had less than 14 days of symptoms prior to testing could be in a pre-seroconversion state. Physicians should interpret such cases with caution. Nonetheless, our data suggests
there is strong correlation between the two assays which is valuable information for different laboratories reporting different results.

Acknowledgements:

We would like to thank Temasek Holdings Pte Ltd for sponsoring the laboratory testing kits used in this study.

Figure Legends:

Figure 1: Linear regression and correlation between Roche and Abbott showing that there was a moderate correlation between both assays with Roche having generally higher quantitative signal outputs.

Figure 2: Bland-Altman plot, showing that the Roche assay has a proportional positive bias as compared to Abbott when signal values increase.

Figure 3a: Scatterplot of Roche total antibody signal values plotted against day of symptom presentation.

Figure 3b: Scatterplot of Abbott IgG antibody signal values plotted against day of symptom presentation.

Figure 4a: Histogram of mean signal values for Roche total antibody, showing that peak signal values are recorded in the >21 days symptoms group.

Figure 4b: Histogram of mean signal values for Abbott IgG, showing that peak signal values are recorded in the 14-20 days symptoms group.

Figure 5: ROC Curve for Roche and Abbott, showing similar AUCs for both assays.
References:


$y = 0.098x + 0.518$

$R^2 = 0.69134$
<table>
<thead>
<tr>
<th>Groups</th>
<th>Mean Roche COI</th>
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<tr>
<td>&gt;21 days</td>
<td>50.00</td>
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<tr>
<td>14-20 days</td>
<td>40.00</td>
</tr>
<tr>
<td>7-13 days</td>
<td>30.00</td>
</tr>
<tr>
<td>&lt;7 days</td>
<td>20.00</td>
</tr>
</tbody>
</table>

Error Bars: +/- 2 SE
The bar chart represents the mean Abbott SCO for different groups based on their duration. The error bars indicate +/- 2 SE.

Groups:
- >21 days
- 14-20 days
- 7-13 days
- <7 days
Sensitivity

Abbott IgG Titre

Roche Total Antibody Titre

1 - Specificity
### Table 1: Qualitative comparison between Roche and Abbott

<table>
<thead>
<tr>
<th></th>
<th>Roche</th>
<th>Total</th>
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<tbody>
<tr>
<td></td>
<td>Non-Reactive</td>
<td>Reactive</td>
</tr>
<tr>
<td>Abbott</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Reactive</td>
<td>96 (56.5%)</td>
<td>8 (4.7%)</td>
</tr>
<tr>
<td>Reactive</td>
<td>5 (2.9%)</td>
<td>61 (35.9%)</td>
</tr>
<tr>
<td>Total</td>
<td>101 (59.4%)</td>
<td>69 (40.6%)</td>
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</table>

Cohen’s Kappa = 0.840, *P*<.001
Table 2: Average Signal values generated by Roche

<table>
<thead>
<tr>
<th>Roche</th>
<th>Average signal values (95% Confidence Interval)</th>
<th>Minimum</th>
<th>Maximum</th>
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</thead>
<tbody>
<tr>
<td>21 days and above</td>
<td>44.18 (32.0 - 56.35)</td>
<td>0.06</td>
<td>100.70</td>
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<tr>
<td>14-20 days</td>
<td>13.68 (8.54-18.81)</td>
<td>0.06</td>
<td>41.90</td>
</tr>
<tr>
<td>7-13 days</td>
<td>5.22 (2.24 - 8.20)</td>
<td>0.06</td>
<td>38.18</td>
</tr>
<tr>
<td>Under 7 days</td>
<td>0.80 (0.21 - 1.39)</td>
<td>0.06</td>
<td>15.69</td>
</tr>
<tr>
<td>Negative cases</td>
<td>0.06 (0.06 - 0.06)</td>
<td>0.05</td>
<td>0.12</td>
</tr>
</tbody>
</table>
Table 3: Average Signal values generated by Abbott

<table>
<thead>
<tr>
<th>Abbott</th>
<th>Average signal values (95% Confidence Interval)</th>
<th>Minimum</th>
<th>Maximum</th>
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<tbody>
<tr>
<td>21 days and above</td>
<td>5.02 (4.01 - 6.02)</td>
<td>0.02</td>
<td>9.64</td>
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<tr>
<td>14-20 days</td>
<td>5.35 (4.09-6.61)</td>
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<td>7-13 days</td>
<td>2.57 (1.51 - 3.63)</td>
<td>0.02</td>
<td>9.31</td>
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<tr>
<td>Under 7 days</td>
<td>0.49 (0.18 - 0.81)</td>
<td>0.01</td>
<td>6.80</td>
</tr>
<tr>
<td>Negative cases</td>
<td>0.07 (0.05 - 0.08)</td>
<td>0.01</td>
<td>0.70</td>
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<tr>
<td>Sample Group</td>
<td>Sensitivity (95% CI)</td>
<td>Roche</td>
<td>Abbott</td>
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<tr>
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<td>----------------------</td>
<td>---------</td>
<td>----------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>90.6% (75.8-96.8%)</td>
<td>84.4% (68.3 – 93.1%)</td>
</tr>
<tr>
<td>≥21 days</td>
<td></td>
<td>85.7% (65.4 – 95.0%)</td>
<td>81.0% (60.0 – 92.3%)</td>
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<tr>
<td>14-20 days</td>
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<td>37.8% (24.1 – 53.9%)</td>
<td>40.5% (26.4 – 56.5%)</td>
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<tr>
<td>7-13 days</td>
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<td>10.0% (5.2 – 18.5%)</td>
<td>8.8% (4.3 – 17.0%)</td>
</tr>
<tr>
<td>&lt;7 days</td>
<td></td>
<td>40.6%(33.5 - 48.1%)</td>
<td>38.8% (31.8-46.3%)</td>
</tr>
<tr>
<td>Overall sensitivity</td>
<td></td>
<td>40.6%(33.5 - 48.1%)</td>
<td>38.8% (31.8-46.3%)</td>
</tr>
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