DEFINITION OF CONTROL THRESHOLDS BY ANOTHER TECHNIQUE FOR IGG TOXOPLASMOSIS AND RUBELLA AS WELL AS FOR ANTI-HEPATITIS C VIRUS ANTIBODIES - BIOGROUP FEEDBACK

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1 BACKGROUND - AIM

For years, a few medical biology laboratories in the Biogroup network have been implementing serological control of certain sensitive parameters, using another technique around the decision cut-off, so as not to return an erroneous result depending on the sensibility or sensitivity of the method to search those parameters. We are presenting the results of the IgG titration for toxoplasmosis and rubella and the search for antibodies (Ab) against the hepatitis C virus (HCV).

2 METHOD

For Atellica IM SIEMENS® users, a control is carried out by an Immulite SIEMENS® kit for all the first research requests for Toxoplasma IgG and Rubella IgG, and any positive HCV serology for Atellica IM SIEMENS® is checked on Cobas e801 ROCHE®.

For Cobas e801 ROCHE® users, Toxoplasma IgG are checked on Vidas BIOMERIEUX® for any equivocal or positive result up to 90 IU/mL, Rubella IgG are checked on Vidas BIOMERIEUX® for any result between 6 and 19 IU/mL and all HCV serologies positive up to an index of 30 or equivocal are checked on Architect ABBOTT®. Each technique is interpreted qualitatively according to the supplier threshold. Secondly, we stratify by slices of index or antibody titer to assess the concordance of the qualitative interpretation of the two techniques.

3 RESULTS

Toxoplasma IgG

For Siemens users : positivity cut-off at 10 IU/mL.
9,155 sera. In view of the results of the interpretations of the two different techniques, **we consider that control by another technique is no longer relevant from a threshold of 20 IU/mL** *(Figure 1).*
For Roche users : positivity cut-off at 30 IU/ml.
1,239 sera. In view of the results of the interpretations of the two different techniques, **we consider that control by another technique is no longer relevant from a threshold of 60 IU/mL** *(Figure 2).*

Figure 1 : Toxoplasma IgG response with Atellica IM SIEMENS® vs qualitive concordance with Immulite SIEMENS®

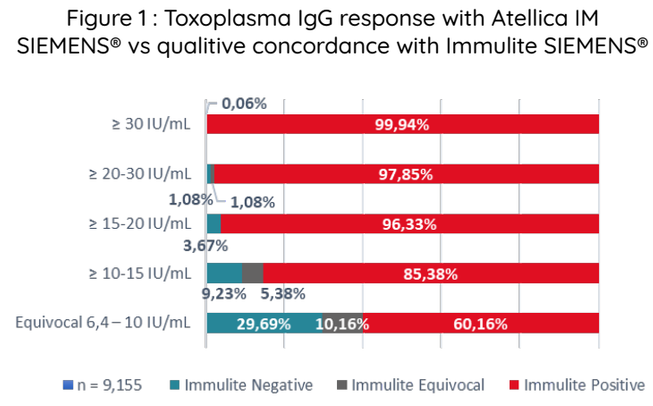
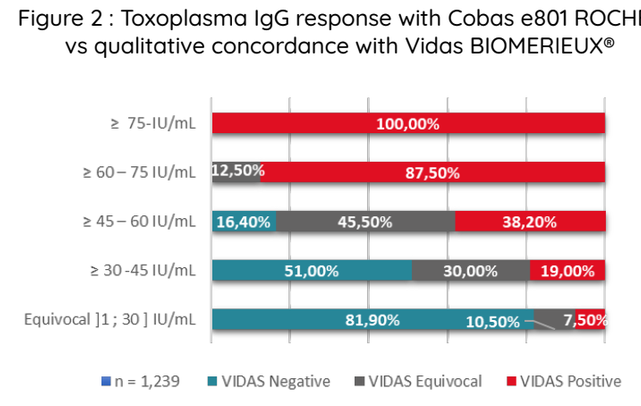


Figure 2 : Toxoplasma IgG response with Cobas e801 ROCHE® vs qualitative concordance with Vidas BIOMERIEUX®



Rubella IgG

For Siemens users : positivity cut-off at 10 IU/mL.
8,213 sera. In view of the results of the interpretations of the two different techniques, **we consider that control by another technique is no longer relevant from a threshold of 15 IU/mL** *(Figure 3).*
For Roche users : positivity cut-off at 10 IU/mL.
1,870 sera. In view of the results of the interpretations of the two different techniques, **we consider that control by another technique is no longer relevant from a threshold of 20 IU/mL** *(Figure 4).*

Figure 3 : Rubella IgG response with Atellica IM SIEMENS® vs qualitative concordance with Immulite SIEMENS®

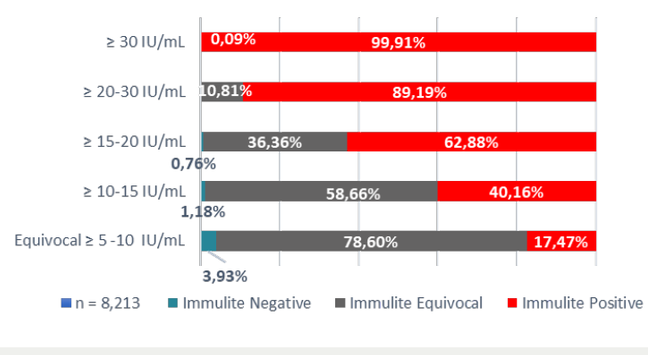
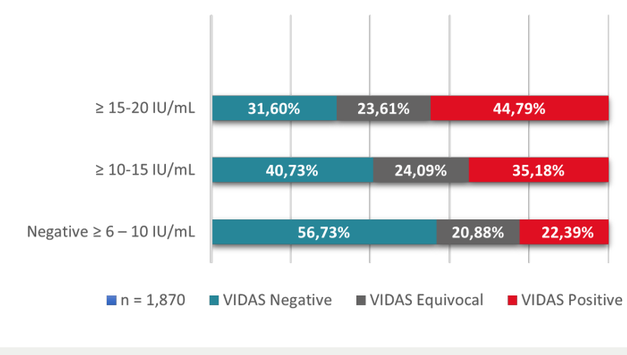


Figure 4 : Rubella IgG response with Cobas e801 ROCHE® vs qualititive concordance with Vidas BIOMERIEUX®



Anti-HCV Ab

For Siemens users : positivity cut-off index at 0.8.
138 sera. In view of the results of the interpretations of the two different techniques, **we consider that control by another technique is no longer relevant from a threshold of index of 10** *(Figure 5).*
For Roche users : positivity cut-off index at 1.0.
571 sera. In view of the results of the interpretations of the two different techniques, **we consider that control by another technique is no longer relevant from a threshold of index of 30** *(Figure 6).*

Figure 5 : HCV antibodies response with Atellica IM SIEMENS® vs qualitative concordance with Cobas e801 ROCHE®

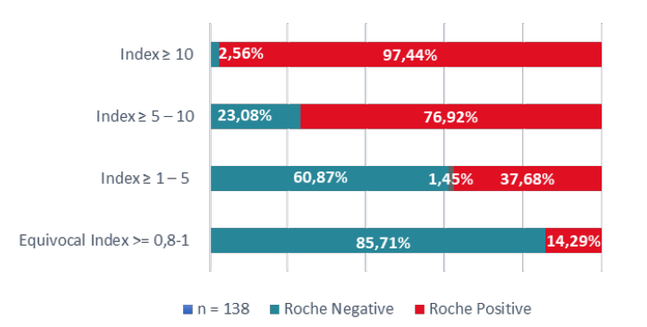
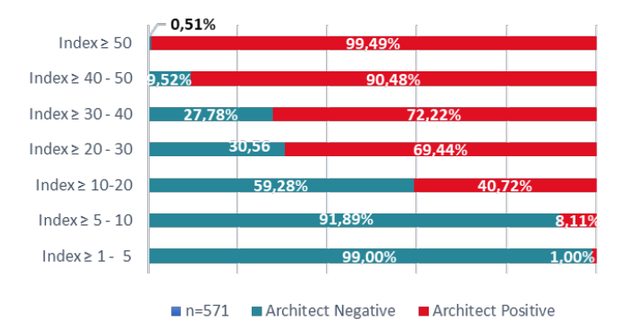


Figure 6 : HCV antibodies response with Cobas e801 ROCHE® vs qualitative concordance with Architect ABBOTT®



4 CONCLUSION

Based on these data, we implemented serological screening with another technique based on the threshold without interpretative deviations. These results confirm that control by another technique is necessary for certain infectious serologies. These controls :

- confirm the specificity of weak positive Toxoplasma IgG while avoiding monthly follow-up of pregnant patients with equivocal results. These results reflect real immunity and deliver the correct information in case of determination of immunological status before immunosuppressive treatment. Furthermore, for each discordant results a Western Blot Toxoplasma IgG will be realized [1];
- provide a good compromise to help understanding the variations around the positivity cut-off of 10 IU/mL for Rubella IgG and confirm that a lot of equivocal results are true positives and show weak titers because of the low viral circulation [2,3];
- objectify real previous contact with HCV in complement of RNA detection [4].

In contrast our study for these 3 parameters shows that immune status, according to the patient, may depend on the technique. Comparing 2 different techniques raises the provider's decision-making threshold to ensure an unequivocal clinical conclusion, extended to that provided only by the calculation of the measurement uncertainty alone. Furthermore, if despite this control by another technique there is still a doubt about the interpretation of the results, the kinetics of the antibodies, studied on a sample taken remotely, will help to decide. These data will be re-evaluated after large-scale implementation and more data about confirmation tests like western blot for Toxoplasma IgG and detection of RNA for HCV.

References

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