

COMPARISON OF DIRECT ANTIGLOBULIN TESTS USING E.M.® TECHNOLOGY AND ORTHO BIOVUE™ SYSTEM

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BACKGROUND

The direct antiglobulin test (DAT) is important in determining if the cause of hemolytic anemia is due to antibodies bound to red blood cells. A new solid phase method for DAT using the process of Erythrocyte Magnetized® Technology (E.M.® Technology) developed by Diagast has been evaluated and compared to the BioVue™ System by Ortho Clinical Diagnostics.

AIMS

The purpose of this study was to compare 2 fully automated DAT techniques on sensitized RBC samples: The E.M.® Technology and the BioVue™ System.

METHODS

Sensitized RBCs from 50 patients were assessed by E.M.® Technology based on IgG & C3d monospecific DAT using the fully automated System **Qwalys® 3** and BioVue™ System based on IgG & C3d monospecific DAT using the fully automated system **Autovue® Innova**.

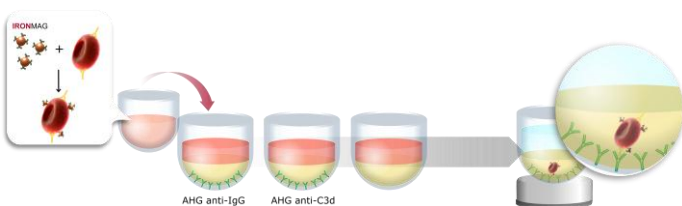


Fig1. Direct antiglobulin test in E.M.® Technology

RESULTS 1/2

Out of 50 samples, 42 samples were positive in both techniques: 5 samples were IgG and C3d positive in both techniques, 30 samples were IgG positive in both techniques, 3 samples were IgG and C3d positive in BioVue™ System and IgG positive in E.M.® Technology, 1 sample was IgG and C3d positive in BioVue™ System and C3d positive in E.M.® Technology, 3 were IgG and C3d positive in E.M.® Technology and IgG positive in BioVue™ System, 7 samples were positive in one technique. 5 samples were IgG positive in BioVue™ System and negative in E.M.® Technology.

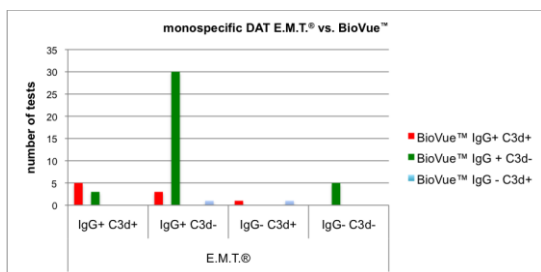


Fig 2. Monospecific DAT results comparison E.M.® Technology vs BioVue™

RESULTS 2/2

All of these samples were weakly positive in BioVue™ System. 1 sample was confirmed negative in E.M.® Technology and in Biorad ID gel technique. 2 samples were retested and detected weakly positive in E.M.® Technology. 2 samples were retested and confirmed negative in E.M.® Technology (these samples couldn't be tested in Biorad ID gel technique), 1 sample was weakly IgG positive in E.M.® Technology and negative in BioVue™ System. This sample was detected weakly positive with BioVue™ polyspecific DAT, 1 sample was weakly C3d positive in E.M.® Technology and negative in BioVue™ System. This sample was detected weakly positive with BioVue™ polyspecific DAT. 1 sample was undetermined in both techniques (negative control and autocontrol are positive).

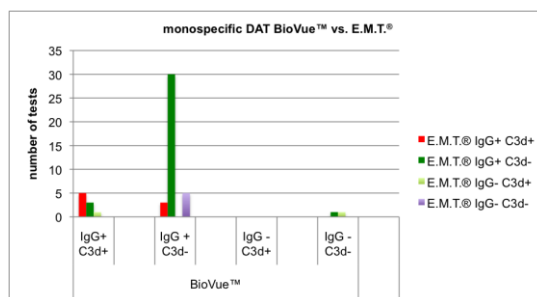


Fig 3. Monospecific DAT results comparison BioVue™ vs E.M.® Technology

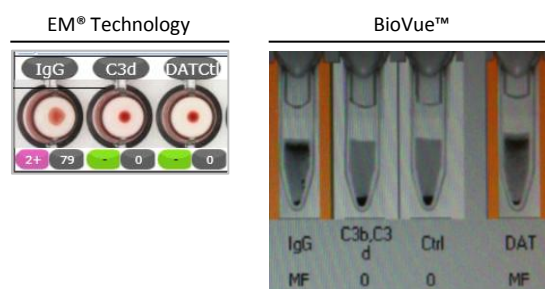


Fig 4. Examples of reactions interpretation E.M.® T vs BioVue™

CONCLUSION

With respectively 91% and 94% of concordance with the expected results, this comparative study shows that the DAT performed with the E.M.® Technology method is as specific and sensitive as the BioVue™ System test for the detection of *in vivo* sensitization of red blood cells by antibodies and/or complement components. The automatic interpretation of the results is more accurate and discriminant with the E.M.® Technology than with the BioVue™ System which 12 samples (24%) are interpreted as "mix field".