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# Validation of a new automated chemiluminescent assay for serodiagnosis of human parvovirus B19 infection.

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**BACKGROUND AND OBJECTIVES**

The aim of this study was to evaluate a new commercial chemiluminescent assay based on recombinant capsid proteins derived from baculovirus for diagnosis of human parvovirus B19 infection. This assay has been adapted by Biotrin International to be fully automated on LIAISON instrument (DiaSorin) using chemiluminescence detection system. We have compared this assay with 4th generation enzyme immunoassay from Biotrin International performed on the Eti-max analyser (DiaSorin).

**METHOD**

A total of 357 sera from routine daily practice (197 for IgM and 160 for IgG) were tested. Discordant results were solved by indirect immunofluorescence (IFI) testing, clinical data's and previous or following serological results when available.
Subsequently, specificity of IgM LIAISON Biotrin assay was assessed in detail by testing 60 serum samples with potentially interfering antibodies (EBV, CMV, HSV, HCV, *Toxoplasma*, *Borrelia*, rheumatoid factor and anti-nuclear antibodies).
Intra-assay and inter-assay imprecision based on samples tested in replicates have been performed for both IgM and IgG.

**RESULTS**

The degree of agreement between the two assay systems was high: 99.2% for parvovirus B19 IgM detection and 95.6% for parvovirus B19 IgG detection. All discordant results (n = 6 for IgM, n = 8 for IgG) were within or close to the equivocal range of each assay. After further analysis with IFI method, 4 out of the 6 discrepant IgM results were correctly tested with LIAISON Biotrin parvovirus IgM assay and 7 out of the 8 discrepant IgG results were correctly tested with LIAISON Biotrin parvovirus IgG assay.
We have not highlighted significant cross- reactions between parvovirus IgM and the other antibodies tested.
Intra-assay and inter-assay imprecision were less than 10% CV for both positive IgM and IgG samples.

**CONCLUSION**

According to our evaluation, the LIAISON parvovirus B19 IgM and IgG assays appear to be a valid alternative for the detection of parvovirus B19 antibodies. These assays combine robust analytical and clinical performance with the advantage of fully automated, random access instrument system. Moreover, LIAISON parvovirus IgG assay shows better specificity than Biotrin 4th generation EIA assay for results close to the equivocal range.