

March 15, 2023

UAB VITROLAB  
Balty Pr. 36 -11,  
KAUNAS, 48196  
LITHUANIA

Dear Raimundas Kaleda,

Thank you for contacting Ortho Clinical Diagnostics regarding your question about Direct Antiglobulin test (DAT) positive control that can be used for Ortho BioVue® System ABO-Rh/DAT (Newborn) Cassettes (Product Code 6901906). This information is needed for a public tender in Lithuania. Your inquiry was registered under the reference number 32202324.

As per product Instructions for Use, ALBAcyte® IgG Sensitised Red Cells (Product Code Z441) are O R1r IgG sensitized cells that can be used as control of Direct Antiglobulin test in BioVue CAT:

- *Ortho BioVue® System (DAT/IDAT Cassette) (Product Code 707165)*
- *Ortho BioVue® System (Poly Cassette) (Product Codes 707350, 707300)*
- *Ortho BioVue® System (IgG Cassette) (Product Codes 707450, 707400)*

ABO-Rh/DAT (Newborn) Cassette column 6 (DAT) contains anti-IgG in 3% PEG similarly to all columns of AHG anti-IgG cassette. Ortho Care Second Level tested the usage of Z441 on ABO-Rh/DAT cassettes on an ORTHO VISION® Analyzer and the expected results were obtained (O Rh pos anti-IgG pos):

Anti-A	Anti-B	Anti-A,B	Anti-D	Control	Anti-IgG
NEG	NEG	NEG	+4	NEG	+4

This Quality Control (QC) is suitable for usage on ORTHO VISION®, ORTHO VISION® Max, and BioVue® manual method (ORTHO® Workstation).

It is our highest priority to maintain customer satisfaction. If you have additional questions, please contact Ortho Care™ Technical Solutions Center at +33 3 88 65 47 21.

Sincerely,

Malgorzata  
Wierzbicka  
(MWIERZBI)

 Digitally signed by Malgorzata  
Wierzbicka (MWIERZBI)  
Date: 2023.03.15 14:17:21  
+01'00'

Malgorzata Wierzbicka

Service Engineer Transfusion Medicine