

VARNOSTNO OBVESTILO

DiaClon Anti-P1, Ref. 007212

Pomembne informacije za DiaClon Anti-P1, Ref. 007212

V vednost profesionalnim uporabnikom v laboratoriju.

Prosimo, shranite to pismo za svojo evidenco.

Datum: 14.11.2025

Bio-Rad Referenca: FA 2025-05

Spoštovani,

Namen tega pisma je, da vas obvestimo o težavi s kakovostjo, povezani z navodili za uporabo (IFU) za DiaClon Anti-P1).

Razlogi za ukrep:

Na podlagi povratnih informacij kupcev in interne preiskave je Bio-Rad ugotovil napako v e-IFU s kodo: B007212 v.02 2024-08-03 — DiaClon Anti-P1 Navodila za uporabo / Smernice za interpretacijo rezultatov. Specifično: rezultati za stopnjo reakcije v epruvetah +, ++, ki bi morali biti razvrščeni kot pozitivni, so bili napačno opisani kot ne-interpretabilni.

Ta neskladnost vpliva na smernice interpretacije rezultatov znotraj IFU. Napačna različica je šibke aglutinacijske stopnje (npr. 1+, 2+) preklasificirala iz **pozitivnih** v rezultate, ki jih ni mogoče interpretirati t.j. **ne-interpretabilne**.

Identifikacija prizadetega izdelka:

DiaClon Anti-P1, Kataloška referenca 007212

e-IFU je dostopen od 9. oktobra 2025 na downloads.bio-rad.com: Koda e-IFU: B007212 v.02 2024-08-03

Ukrepi, ki jih mora izvesti uporabnik:

Bio-Rad priporoča naslednje korake:

- Zavrzite e-IFU B007212 v.02 2024-08-03
- Zamenjajte ga z novo različico B007212 v.02.1 2025-11-04. Nova različica je na voljo za prenos na spletni strani "Download.bio-rad.com", kot je navedeno na etiketi škatle.



B007212

downloads.bio-rad.com



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Prosimo, poskrbite, da bodo s tem obvestilom seznanjene tudi vse relevantne osebe v vaši organizaciji in morebitni zunanji uporabniki, ki uporabljajo prizadete izdelke.

Prosimo, izpolnite in vrnite priložen odzivni obrazec, da potrdite prejem tega pomembnega obvestila.

Rešitev s strani Bio-Rada:

Popravljen različica navodil za uporabo (IFU) je bila naložena pod novo kodo e-IFU: B007212 v.02.1 2025-11-04 in je na voljo na zgoraj navedeni strani. Spremembe so za jasnost označene s sivo bravo.

Primer sprememb med objavljeno različico v.02 in popravljen različico v.02.1 je prikazan spodaj:

B007212 v.02 2024-08-03 / Napačna različica		
Well Reaction Grade	Reaction Description	Result Interpretation
-	A flat and compact pellet of RBCs with a smooth surface at the bottom of the well with no visible agglutination.	Negative (indicates an absence of the corresponding antigen)
+/-	A pellet of RBCs at the bottom of the well with very few agglutinated RBCs visible above the pellet or an irregular pellet.	Non-interpretable (further investigations are required)
+	A pellet of RBCs at the bottom of the well with agglutinated RBCs visible in the lower half of the gel column.	
++	Agglutinated RBCs distributed throughout the entire length of the gel column, with no line of RBCs on the top of the well.	
+++	Most agglutinated RBCs concentrated at the top of the gel or upper half of the gel column.	Positive (indicates the presence of the corresponding antigen)
++++	Agglutinated RBCs concentrated as a line on the top of the gel column with a few agglutinated RBCs just underneath the gel surface.	
dp: double population	Agglutinated RBCs as a line at the top of the gel or dispersed in the upper part of the gel and non-agglutinated RBCs forming a pellet at the bottom of the well.	Non-interpretable (further investigations are required)

B007212 v.02.1 2025-11-04 / Popravljen različica		
Well Reaction Grade	Reaction Description	Result Interpretation
-	A flat and compact pellet of RBCs with a smooth surface at the bottom of the well with no visible agglutination.	Negative (indicates an absence of the corresponding antigen)
+/-	A pellet of RBCs at the bottom of the well with very few agglutinated RBCs visible above the pellet or an irregular pellet.	Non-interpretable (further investigations are required)
+	A pellet of RBCs at the bottom of the well with agglutinated RBCs visible in the lower half of the gel column.	Positive (indicates the presence of the corresponding antigen)
++	Agglutinated RBCs distributed throughout the entire length of the gel column, with no line of RBCs on the top of the well.	
+++	Most agglutinated RBCs concentrated at the top of the gel or upper half of the gel column.	
++++	Agglutinated RBCs concentrated as a line on the top of the gel column with a few agglutinated RBCs just underneath the gel surface.	
dp: double population	Agglutinated RBCs as a line at the top of the gel or dispersed in the upper part of the gel and non-agglutinated RBCs forming a pellet at the bottom of the well.	Non-interpretable (further investigations are required)



Kontaktne informacije:

Za vsa vprašanja v zvezi s tem obvestilom se obrnite na tehnično podporo Bio-Rad.

- Spletna tehnična podpora in kontakti po svetu so na voljo na:
<https://www.bio-rad.com/contact>.

Bio-Rad zagotavlja, da ostaja naša najvišja prioriteta zagotavljanje visoke ravni varnosti in kakovosti. Ob tem se opravičujemo za morebitne nevspečnosti.

Elizabeth Platt

VP, Quality, Regulatory & Clinical Affairs
Bio-Rad Laboratories Inc.



Enclosure:
FIELD ACTION RESPONSE FORM

FIELD ACTION RESPONSE FORM
Bio-Rad Reference: FA 2025-05
Bio-Rad Product Segment: IH
Single Registration Number (SRN): CH-MF-000020826

PRODUCT

DiaClon Anti-P1, Catalog Reference 007212
<i>e-IFU available since October 09th, 2025 in downloads.bio-rad.com: e-IFU code number B007212 v.02 2024-08-03</i>

CUSTOMER / CHANNEL PARTNER INFORMATION

Account Name:	
Undersigning Manager Name:	
Address:	
Telephone Number / Fax:	
Account Number:	

STATEMENT:

- No affected product received
- I am aware of the information about the field action concerning the above reference product(s) and have proceeded according to the instructions issued by Bio-Rad.
- <Omit/include, as needed>* For completion by Channel Partners: All customers have been informed about this field action and have proceeded according to the instructions issued by Bio-Rad. Number of customers informed: _____

Number of affected products received:	N/A	Number of affected products corrected/ destroyed/ returned (as applicable to the Field Action instructions):	N/A
If number of products corrected/ destroyed/ returned is different to the number received, please account for the difference: N/A			

Date:
 Customer / Channel Partner Signature (and Stamp if applicable)
 Please return this form to: **info@diahem.si**