

Product Name	FabRICATOR® Validation Kit 2000u
Product No	A0-FR4-060
Product Lot Numbers	A0FR1-9F22F A0FR1-10C17H A0FR1-10D05H
Product Composition	FabRICATOR®, proteolytic enzyme for antibody fragmentation, as lyophilized powder with different lot numbers
Manufacturer	Genovis AB
Storage Temp	-20 °C

TEST

SPECIFICATION

Appearance	White to light yellow powder
Purity by HPLC-SEC	95 % ± 5%
Purity by SDS-PAGE	>90 % visual estimation
Enzyme activity by HPLC-SEC	≥ 95 % digested hIgG
Enzyme activity by SDS-PAGE	> 95 % digested hIgG visual estimation
Bioburden*	0 cfu/vial

* Tested on Sabouraud dextrose Agar, Fluid Thioglycollate Medium and Sheep Blood Agar

RESULTS

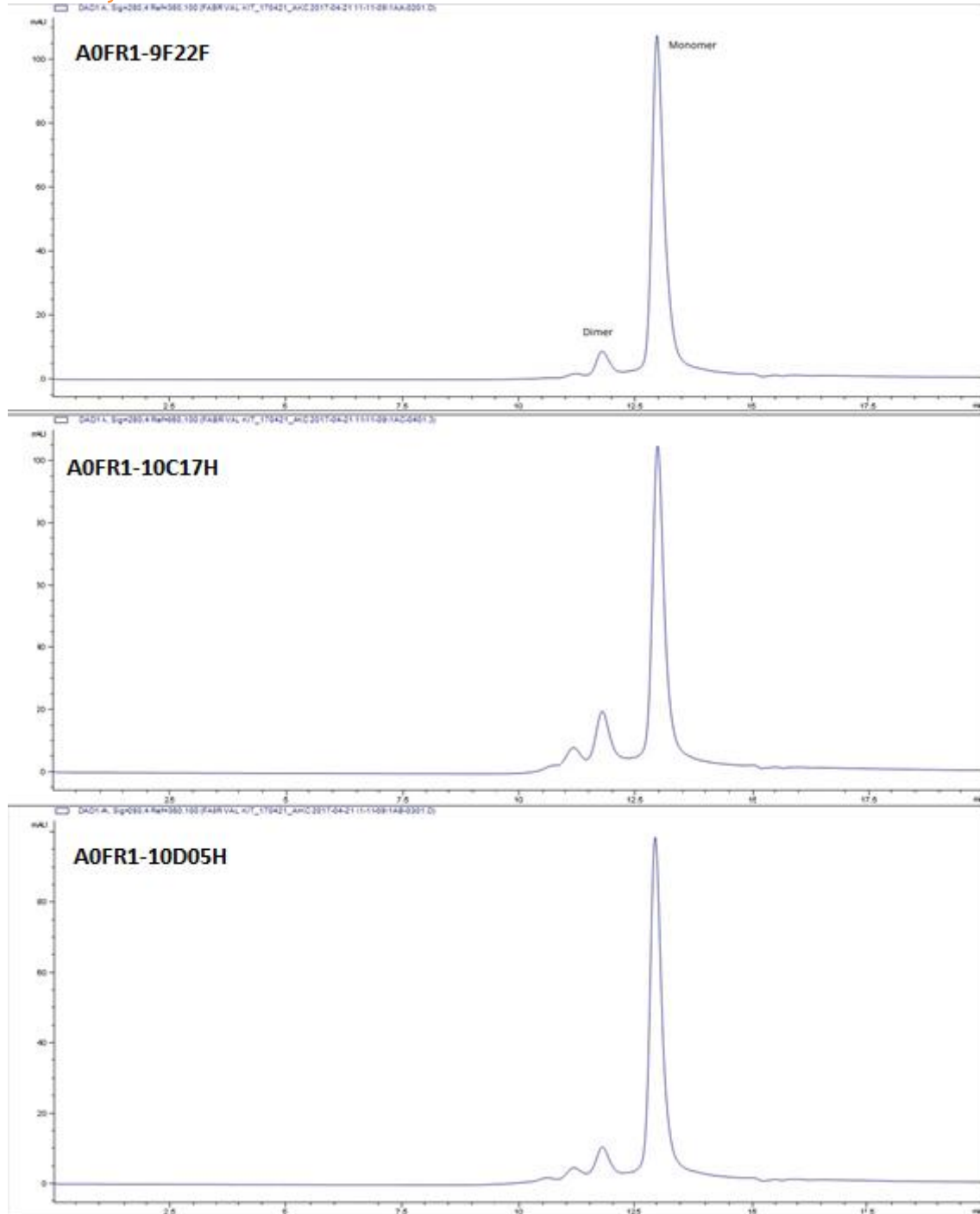
TEST	A0FR1-9F22F	A0FR1-10C17H	A0FR1-10D05H
Appearance	PASS	PASS	PASS
Purity by HPLC-SEC	98%	93%	95%
Purity by SDS-PAGE	PASS	PASS	PASS
Enzyme activity by HPLC-SEC	98%	98%	98%
Enzyme activity by SDS-PAGE	PASS	PASS	PASS
Bioburden	0 cfu/vial	0 cfu/vial	0 cfu/vial

Telephone: +46 (0)46 10 12 30
 Telefax: +46 (0)46 12 80 20
 E-mail: info@genovis.com
 Internet: www.genovis.com

Visiting address:
 Medicon Village
 Scheelevägen 2
 SE-223 63 Lund
 Sweden

Postal address: Box 790
 SE-223 07 Lund
 Sweden
 VAT number: SE556574534501

PURITY by HPLC-SEC



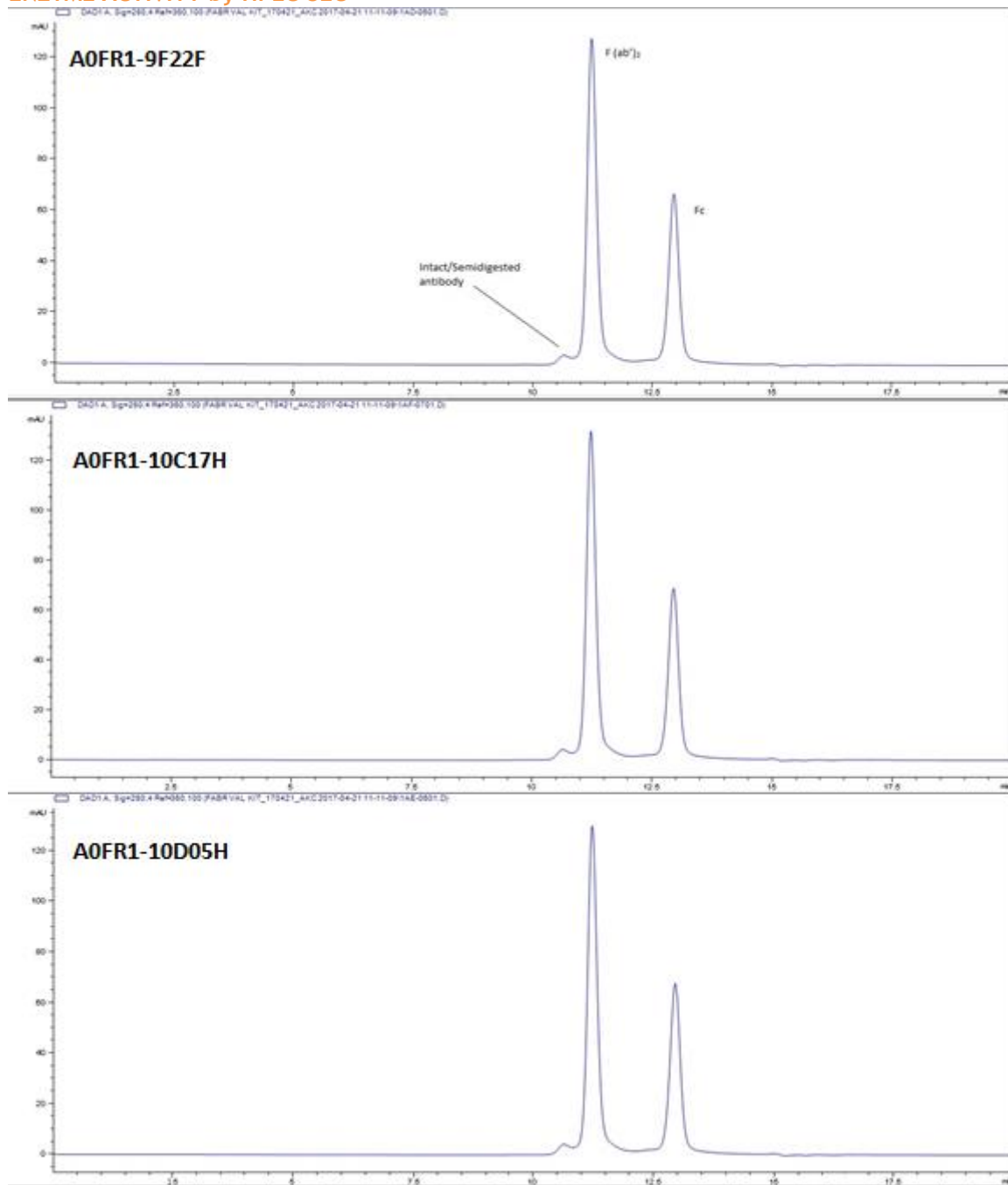
FabRICATOR® is active both as dimer and monomer.

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ENZYME ACTIVITY by HPLC-SEC



100µg Humira® (Adalimumab, AbbVie) with 100u FabRICATOR® in 10mM PBS pH 7.4. 30 min digestion at 37°C.

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ENZYME ACTIVITY and PURITY by SDS-PAGE



100µg mAb with 100u FabRICATOR® in 10mM PBS pH 7.4. 30 min digestion at 37° C.
mAb used: Humira® (Adalimumab, AbbVie) and Avastin® (Bevacizumab, Roche).

Well 1-8: Activity of batches

1. Marker
2. Humira®
3. Humira® + FabRICATOR® A0FR1-9F22F
4. Humira® + FabRICATOR® A0FR1-10D05H
5. Humira® + FabRICATOR® A0FR1-10D17H
6. Avastin®
7. Avastin® + FabRICATOR® A0FR1-9F22F
8. Avastin® + FabRICATOR® A0FR1-10D05H
9. Avastin® + FabRICATOR® A0FR1-10C17H

Well 10-12: Purity of batches

10. FabRICATOR® A0FR1-9F22F
11. FabRICATOR® A0FR1-10D05H
12. FabRICATOR® A0FR1-10C17H

Linda Andersson
Production manager
Genovis AB, Lund, SWEDEN

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