

Testing Report Nr. 1504-FY-98167 - Request complete

Customer's data

Customer: **Private** Payer: **Customer personally**
 Address: [REDACTED] Report receiver: **Customer personally**
 Phone: [REDACTED]
 E-mail: [REDACTED]

Report details

Analysis Report: **No 190302** Analyze Type: **Detailed**
 Reception Date: **2021-12-01** Sample Characteristic: **Appropriate for testing**
 Analyze Date: **2021-12-02** Sample Package: **Sterile solution**

Tested substance according to manufacturer's datas

Substance: **Recombinant Human Growth Hormone (Somatropin)** Special temperature storage conditions for samples are required
 Brand: **Unbranded product**
 Dosage: **100 IU set, 2 vials of 5 ml, 33.3 mg (16.5 mg/vial)** YES NO
 Sample description: **Hermetically closed, crimp top vials**
 Batch: **FL-8149**
 Exp. date: **12 2024**

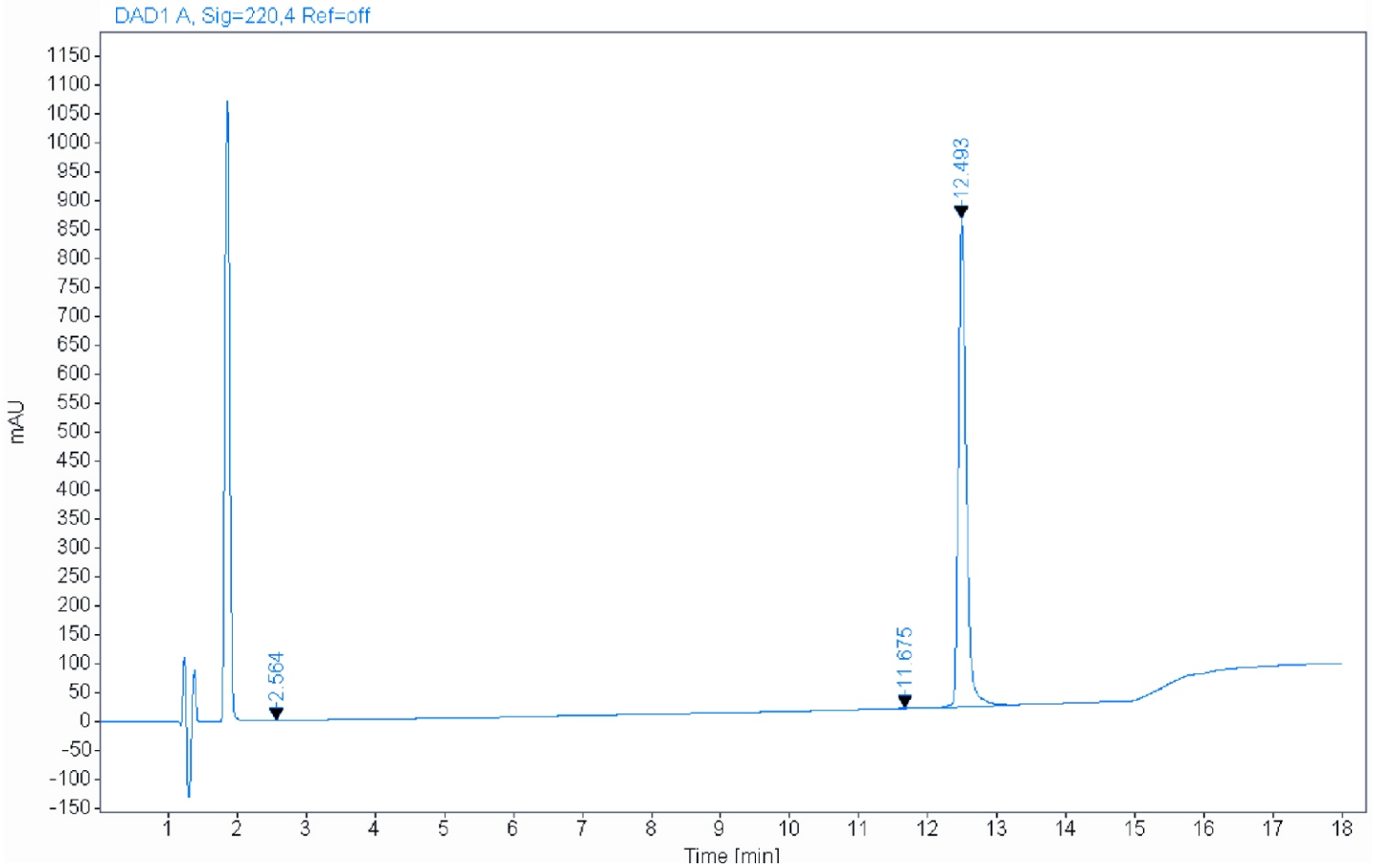
Analysis	Method	Equipment	Result	EP requirements
Identification	HPLC (EP 2.2.29)	Agilent 1100	COMPLIES	
Assay	HPLC (EP 2.2.29)	Agilent 1100	3,34 mg/ml	89-105% of the stated on the label
Area% (Purity)	HPLC (EP 2.2.29)	Agilent 1100	99,37%	≥ 95%
Host-cell-derived proteins	ELISA	Cygnus F410	2 ng/mg	0-200 ng/mg
Host-cell and vector-derived DNA	PicoGreen®	Cygnus D420t	11 ng/mg	0-30 ng/mg
Bacterial endotoxins	Gel-clot method (EP 2.6.14)	Pyrotell #G5125-25	2 IU/mg	0-5 IU/mg
Sterility	Membrane filtration (EP 2.6.1)	0.45µ cellulose nitrate filter	STERILE	

Analysis Report



Agilent Technologies

Data file: C:\CHEM32\3\DATA\HGH\Sample-98167
2021-12-02 18-07.D
 Sample name: Sample-98167
 Sample amount: 20.000 Sample type: Sample
 Instrument: HPLC Location: Vial 2
 Injection date: 12/02/2021 5:56:53 PM Injection: 1 of 1
 Acq. method: TEST.M Injection volume: 20.000
 Analysis method: HGH TEST.M Acq. operator: SYSTEM
 Last changed: 12/02/2021 6:31:24 PM



Signal: DAD1 A, Sig=220,4 Ref=off



Agilent Technologies

RT [min]	Type	Width [min]	Area	Height	Area%	Name
2.564	BV	0.1038	6.6474	1.0229	0.0996	
11.675	BB	0.1620	21.3451	2.0419	0.3197	
12.493	BB	0.1198	6649.0649	844.7393	99.5808	
Sum			6677.0574			

Module	Type	Part. No.	Serial No.	Firmware
Quat. Pump	Pump	G1311A	DE43631367	A.07.01 [001]
DAD	Detector	G1315B	DE11111836	A.07.02 [001]
Column Comp.	Column compartment	G1316A	DE43412580	A.07.02 [001]
Sampler	Auto sampler	G1329A	DE43274128	A.07.02 [005]

Validated:

Approved by: _____
 Signature: _____
 Date: 2/12/2021