

Certificate of Analysis / Quality Control Verification

Certificate of analysis

Keyref	130C02	This documents certifies this product has met the APTEC Diagnostics nv Quality Control requirements. Nancy Van Gysel Quality Control Manager
Product Description	α1-Antitrypsin Antiserum	
Lot Number	AL03396	
Expiration Date	2023/10	
Date of Manufacture	2018/10	



Specifications

Source	Goat	Preservative	0.095 % Na Azide
State	Delipidated, defibrinated	Buffer	Phosphate buffered saline
Specificity	Monospecific on crossed IEP	Storage	2 - 8 °C

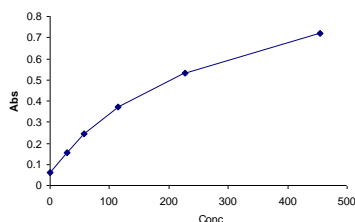
Performance

Reagents

Product Description	Keyref	Lot Number	Expiry date
α1-Antitrypsin Antiserum	130C02	AL03396	2023/10
α1-Antitrypsin Buffer	130C03	AL02797	2023/01
Protein Standard Set	124E17	AL03372	2021/02

Calibration

Concentration	Absorption
0.00	0.05959
28.00	0.15302
57.00	0.24565
114.00	0.36964
227.00	0.53305
454.00	0.72070



Intrareproducibility

n	10	mean	155.80	SD	2.9048	VC	1.8644
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Controls

Description	Lot Number	Assigned	Measured
APTEC Immunology Control Low	AL03301	73.9 (62.8 - 85.0) mg/dL	75.8 mg/dL
APTEC Immunology Control High	AL03300	153 (130 - 176) mg/dL	156 mg/dL
SIEMENS Protein Control SL/M	084752	155 (132 - 178) mg/dL	156 mg/dL
BIORAD Liquichek Immunology Control Level 1	66371	79.1 (55.6 - 103) mg/dL	84.3 mg/dL



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Keyref	122C03	This documents certifies this product has met the APTEC Diagnostics nv Quality Control requirements. Nancy Van Gysel Quality Control Manager
Product Description	α1-Acid Glycoprotein Buffer	
Lot Number	AL02797	
Expiration Date	2023/01	
Date of Manufacture	2018/01	

**Quality Control Specifications**

Parameter	Specification	Result
Colour	Colourless	OK
Odour	Odourless	OK
Clarity	Clear	OK

Quality Control

Quality Control on Pentra 400 has met APTEC Quality Control requirements.