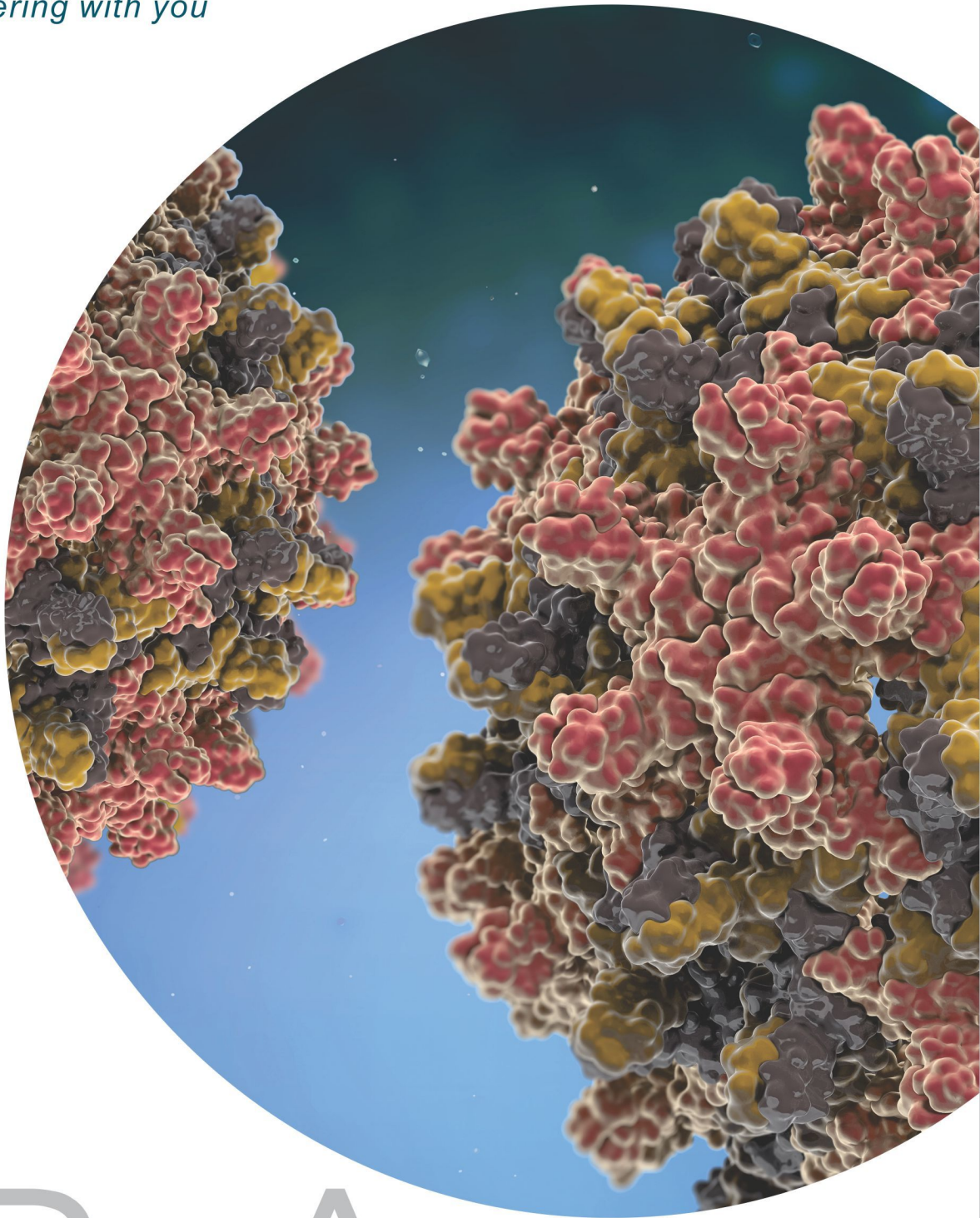




ADVY

Partnering with you



HBsAg

HEPATITIS B SURFACE ANTIGEN

SALIENT FEATURES

- Manufactured from **HBV positive Blood Units**
- **Blood units are sub-typed for Ad & Ay and segregated**
- Process controlled by using dedicated containers for Ad and Ay
- Stable manufacturing process for 10+ years
- Lot size can be customized from 50 mgs to 500 mgs
- HBsAg Concentration/ml can be customized for your application
- Tested for HIV ½ and HCV Viral Marker by ELISA and PCR
- High purity (>95%) by SDS-PAGE
- Stable for >3 years at 2-8°C and up to 5 years at -20°C (in working aliquots). Studies continue.
- Material remains safe for up to 2-3 freeze-thaw cycles when thawing is done at 2-8°C
- Heat Inactivated at 60°C for 16 hours (WHO & USFDA)
- Processed at EHS compliant facility under ISO 13485 QMS by trained man-power
- Shipment can be made in preferred aliquots. (Nalgene pre-sterilized bottles used)
- Labeling compliant with global regulatory requirements
- Secondary and Tertiary packaging validated for cold-chain shipment for up to 5 days

SUITABILITY

- As immunogen (use only azide free) for raising polyclonal and monoclonal antibodies
- As antigen for making controls and calibrators in Turbidimetry, Nephelometry, ELISA and CLIA based qualitative & quantitative assays
- Preparation of columns for purification of Anti-HBS antibodies

SPECIFICATION

Test Parameters

Physical Appearance
HBsAg Concentration
HBsAg Concentration

Shelf life
Buffer details

% Purity
SDS PAGE

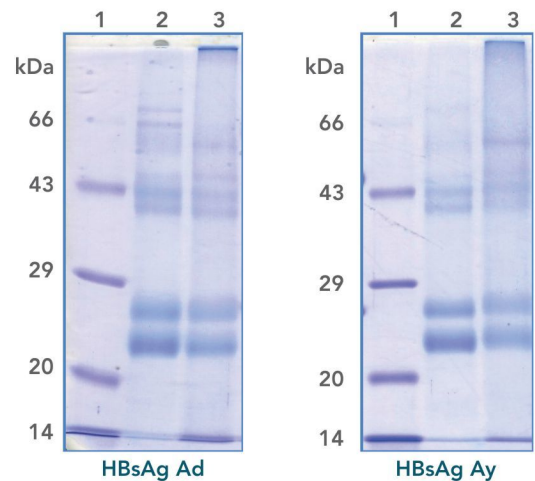
Anti HIV 1&2
Anti HCV
HIV DNA
HCV RNA
Bioburden Load
(Bulk Shipment only)

Storage conditions

Acceptance Criteria

Opalescent protein solution
Range 1.0 – 5.0 mg/ml (ELISA)
Range 1.0 – 5.0 mg/ml
(OD at 280nm)
3 years
Phosphate buffer 20mM at
pH7.4 ± 0.2 containing
150 mM NaCl,
5% Sucrose and 15mM NaN₃
≥ 95% for High pure
Bands of Molecular wt. P24, gp27,
P33 and gp36
Negative (ELISA Assay)
Negative (ELISA Assay)
Not Detected (PCR Analysis)
Not Detected (PCR Analysis)
≤ 10 cfu/ml
2 to 8° C

SDS-PAGE PROFILE



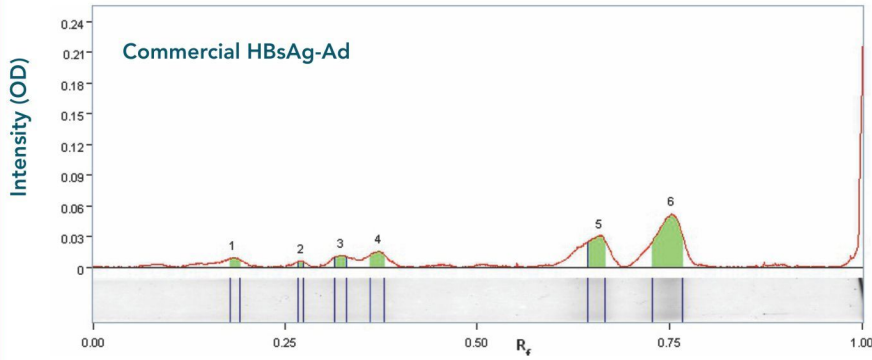
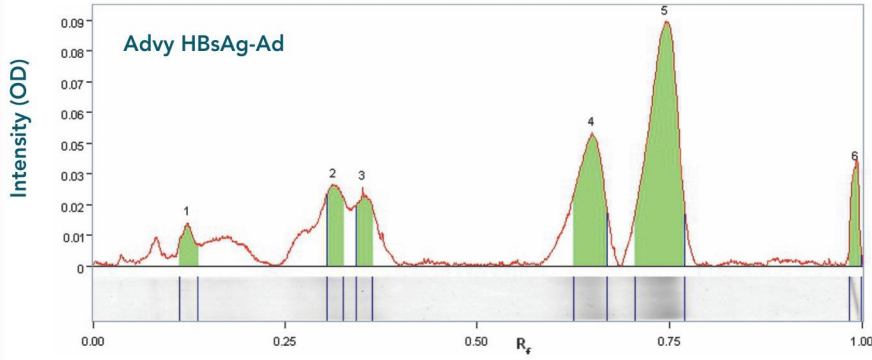
12% Reducing SDS-PAGE

Lanes	Sample Detail Ad
1	Marker Protein
2	HBD # 012/0218 (7µg)
3	Commercial HBsAg Ad (7µg)

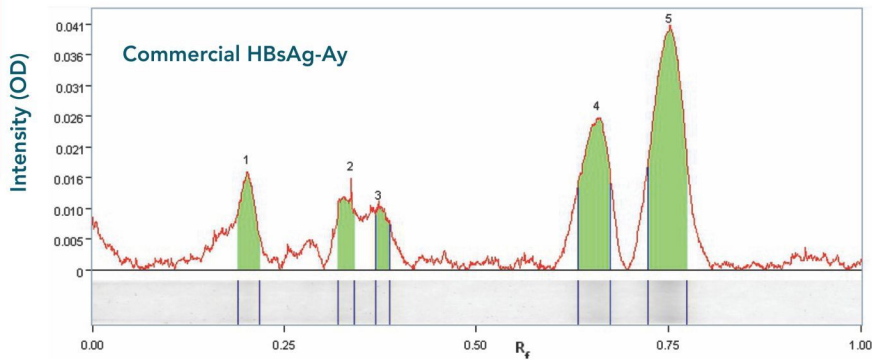
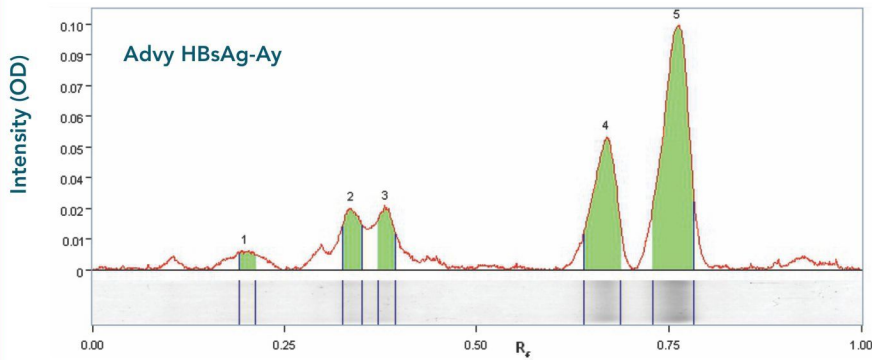
Lanes	Sample Detail Ay
1	Marker Protein
2	HBV # 011/1018 (7µg)
3	Commercial HBsAg Ay (7µg)

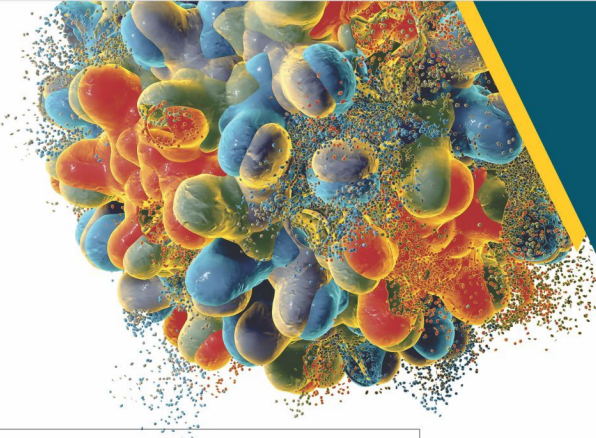
TYPICAL SDS-PAGE GEL SCANNING COMPARISON SHOWING PROPORTIONS OF DIFFERENT BANDS

Typical SDS-PAGE (reduced) gel scanning comparison showing proportions of different bands

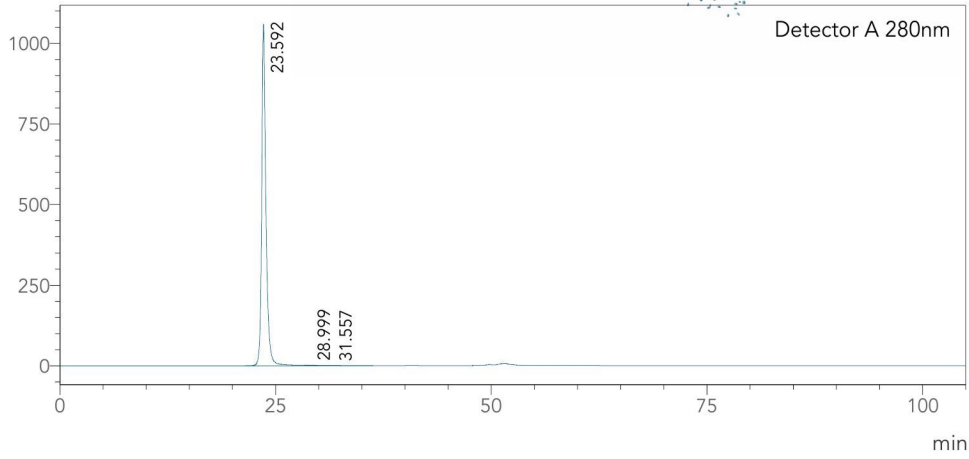


Comparison between profile of Advy HBsAg Ay and Commercial HBsAg Ay





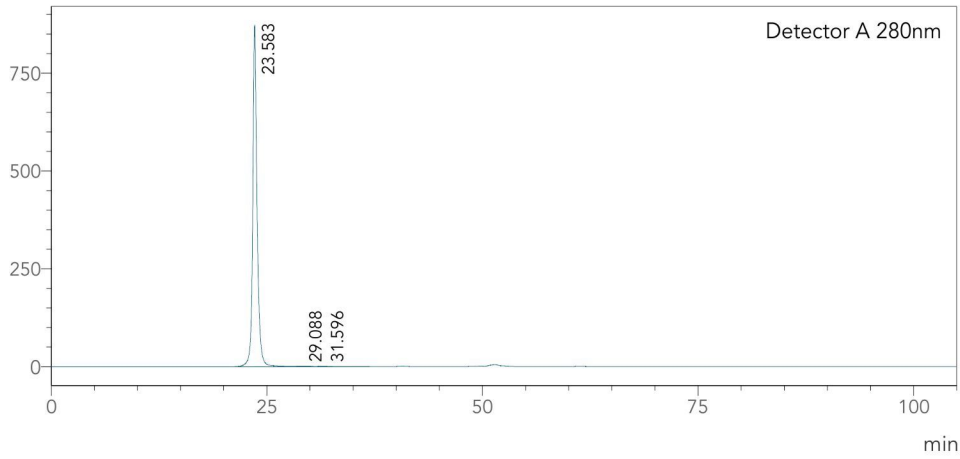
SEC-HPLC PURITY PROFILE HBsAg-Ad



Detector A 280nm

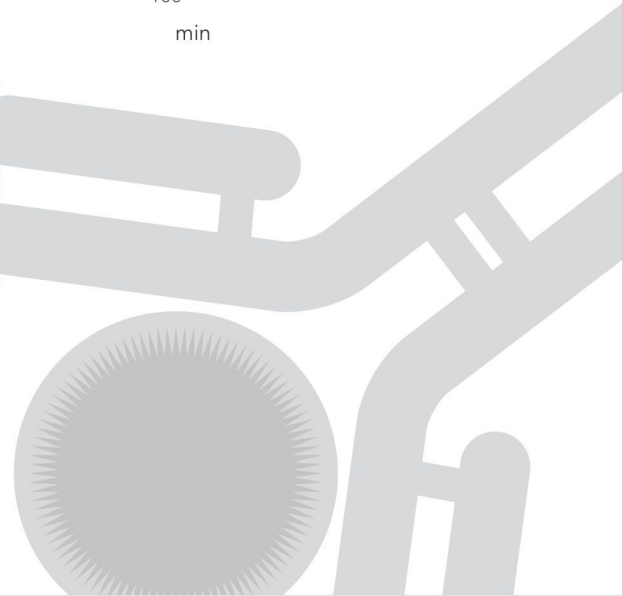
Peak#	Ret. Time	Area	Area%	Height
1	23.592	36662665	99.918	1056975
2	28.999	24392	0.066	494
3	31.557	5804	0.016	110
Total		36692860	100.000	1057580

SEC-HPLC PURITY PROFILE HBsAg-Ay

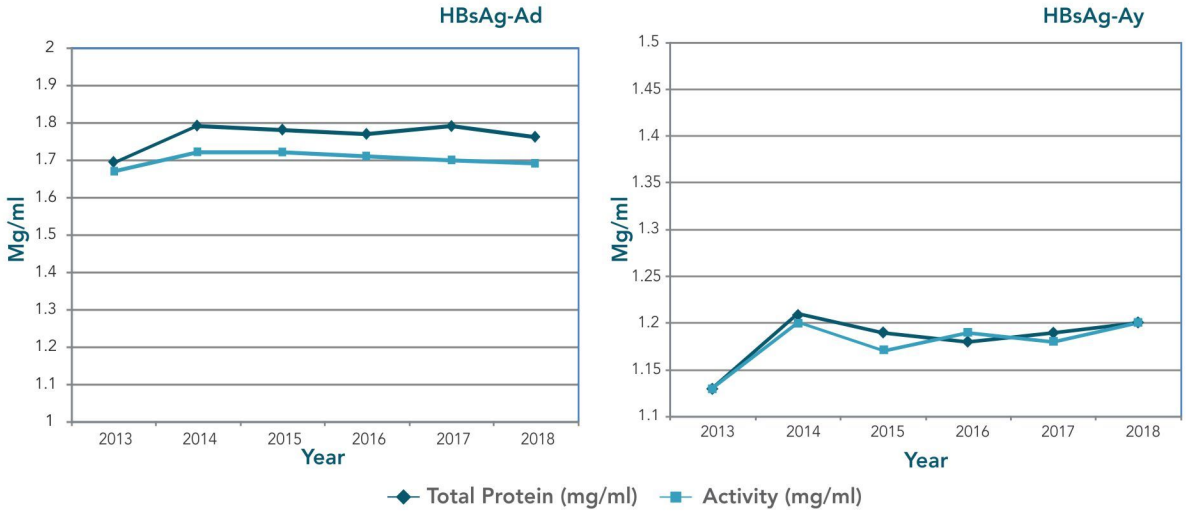


Detector A 280nm

Peak#	Ret. Time	Area	Area%	Height
1	23.583	30759521	99.931	868593
2	29.088	13794	0.045	267
3	31.596	7444	0.024	137
Total		30780759	100.000	868996

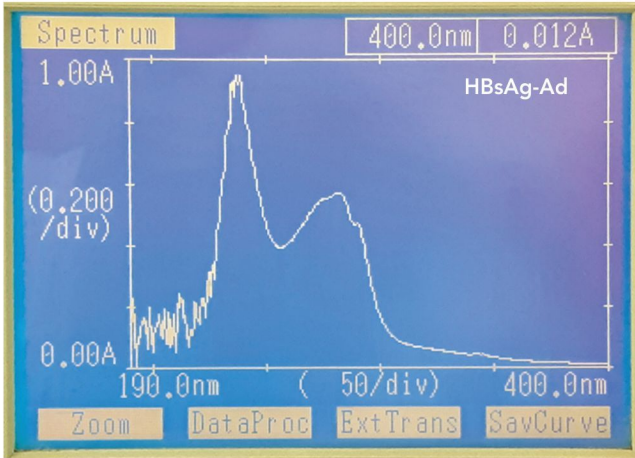


STABILITY PROFILE OF HBsAg

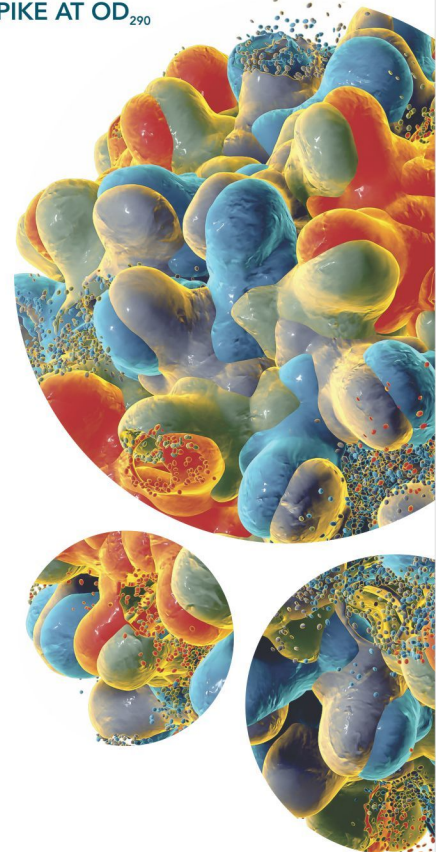
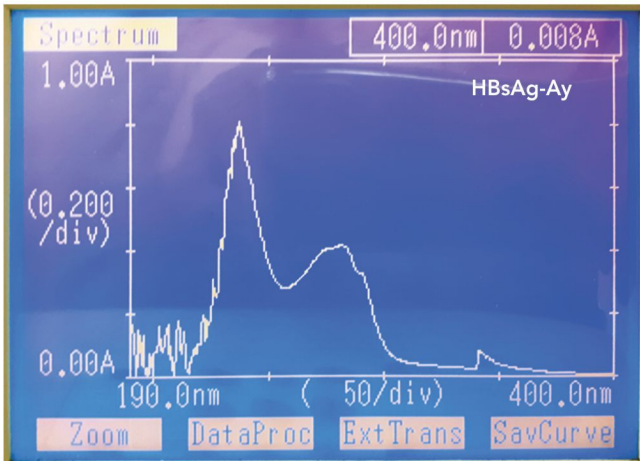


Both HBsAg Ad and Ay antigens are stable for up to 5 years when stored at 2-8° C

ABSORPTION MAXIMA



HBsAg PREPARATIONS SHOWING TYPICAL PEPTIDE BOND MAXIMA AT OD₂₃₀ AND TRYPTOPHAN MAXIMA AT OD₂₈₀ WITH SPIKE AT OD₂₉₀





ADVY

Partnering with you

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