

## CERTIFICATE OF ANALYSIS

**Important Note:** Centrifuge before opening to ensure complete recovery of vial contents.

**Catalog #:** K07110H **Lot #:** 2I27322

**Description:** Positive Control Set For Autoimmune  
Positive Control Set (SS-A, SS-B, Sm, nRNP, Scl-70, Jo-1)

**Specificity:** Set Includes:

Catalog# K07103H	Human anti Human Ro (SS-A) Antigen	Lot# 7A02617
Catalog# K07104H	Human anti Human SS-B Antigen	Lot # 16A01918
Catalog# K07105H	Human anti Human Sm Antigen	Lot# 5A02617
Catalog# K07108H	Human anti Human RNP Antigen	Lot# 4F17417
Catalog# K07102H	Human anti Human Scl-70 Antigen	Lot# 3D11016
Catalog# K07101H	Human anti Human Jo-1 Antigen	Lot# 1I25622

**Host Animal:** Human Plasma

**Format:** Purified, Lyophilized  
Reconstitute with 2 mL deionized water.

**Purification:** Single donor human plasma is delipidized and defibrinated. An immunoglobulin fraction is then precipitated and collected.

**Concentration:** Not Applicable

**Buffer:** Lyophilized from 0.01 M Phosphate, 0.13 M Sodium Chloride, pH 7.2.

**Preservative:** 0.02% Sodium Azide (prior to lyophilization).

**Application:** Suitable for use in Immunodiffusion and ELISA. Each laboratory should determine an optimum working titer for use in its particular application. Other applications have not been tested but use in such assays should not necessarily be excluded.

**Storage:** Store at  $\leq 0^{\circ}\text{C}$ . Avoid multiple/freeze thaw cycles.

**Safety Note(s):** Refer to the appropriate Safety Data Sheet (SDS) for additional information.

Quality Signature:



30 Sep 2022

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**Catalog #:** K07103H **Lot #:** 7A02617

**Description:** Human anti-Ro (SS-A) Antigen  
Human Antibody to Ro (SS-A) Antigen

**Specificity:** Shows only the SSA precipitate band when tested using double immunodiffusion against bovine spleen extract (BSE-1000). Specificity is verified by identity of precipitation with CDC-AF reference serum. Titer will vary with test system; however, undiluted antibody shows a strong SSA precipitate band. Exhibits no reactivity at a dilution of 1:100 when tested against purified SSB, Scl-70, Sm, Sm/RNP, and Jo-1 antigens in an ELISA system designed to detect all IgG subclasses.

**Source:** Human Plasma

**Format:** Purified, Lyophilized  
Reconstitute with 2 mL deionized water.

**Purification:** Single donor human plasma is delipidized and defibrinated. An immunoglobulin fraction is then precipitated and collected.

**Concentration:** Not Applicable

**Buffer:** Lyophilized from 0.01 M Phosphate, 0.13 M Sodium Chloride, pH 7.2.

**Preservative:** 0.02% Sodium Azide (prior to lyophilization).

**Application:** Suitable for use in Immunodiffusion and ELISA. Each laboratory should determine an optimum working titer for use in its particular application. Other applications have not been tested but use in such assays should not necessarily be excluded.

**Storage:** Store at ≤ 0°C. Avoid multiple/freeze thaw cycles.

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**Important Note:** Centrifuge before opening to ensure complete recovery of vial contents.

**Catalog #:** K07104H **Lot #:** 16A01918

**Description:** Human anti Human SS-B Antigen  
Human Antibody to Human La/SSB Antigen

**Specificity:** Shows only the La/SSB precipitate band when tested using double immunodiffusion against rabbit thymus extract. Specificity is verified by identity of precipitation with CDC-AF reference serum. The titer obtained will vary with the test system; however, undiluted antibody shows a strong La/SSB precipitate band. Product shows no reactivity at a dilution of 1:100 when tested against purified Scl-70, Sm, Sm/RNP, and Jo-1 antigens in an ELISA system designed to detect all IgG classes. Anti-SSA activity is detected in this ELISA system.

**Source:** Human Plasma

**Format:** Purified, Lyophilized  
Reconstitute with 2 mL deionized water.

**Purification:** Single donor human plasma is delipidized and defibrinated. An immunoglobulin fraction is then precipitated and collected.

**Concentration:** Not Determined

**Buffer:** Lyophilized from 0.01 M Phosphate, 0.13 M Sodium Chloride, pH 7.2.

**Preservative:** 0.02% Sodium Azide (prior to lyophilization).

**Application:** Suitable for use in Immunodiffusion and ELISA. Each laboratory should determine an optimum working titer for use in its particular application. Other applications have not been tested but use in such assays should not necessarily be excluded.

**Storage:** Store at ≤ 0°C. Avoid multiple/freeze thaw cycles.

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**Important Note:** Centrifuge before opening to ensure complete recovery of vial contents.

**Catalog #:** K07108H **Lot #:** 4F17417

**Description:** Human anti Sm Antigen  
Human Antibody to Sm (Smith) Antigen

**Specificity:** Shows the Sm precipitate band when tested using double immunodiffusion against rabbit thymus extract. Specificity is verified by identity of precipitation with CDC-AF reference serum. Anti-RNP precipitant is also detected. Titer will vary with test system; however, undiluted antibody shows a strong Sm precipitate band. Exhibits no reactivity at a dilution of 1:100 when tested against purified SSB, Scl-70 and Jo-1 antigens in an ELISA system designed to detect all IgG subclasses. Anti-RNP and low levels of anti-SSA activity are detected in this ELISA system.

**Source:** Human Plasma

**Format:** Purified, Lyophilized  
Reconstitute with 2 mL deionized water.

**Purification:** Single donor human plasma is delipidized and defibrinated. An immunoglobulin fraction is then precipitated and collected.

**Concentration:** Not Determined

**Buffer:** Lyophilized from 0.01 M Phosphate, 0.13 M Sodium Chloride, pH 7.2.

**Preservative:** 0.02% Sodium Azide (prior to lyophilization).

**Applications:** Suitable for use in Immunodiffusion and ELISA. Each laboratory should determine an optimum working titer for use in its particular application. Other applications have not been tested but use in such assays should not necessarily be excluded.

**Storage:** Store at  $\leq 0^{\circ}\text{C}$ . Avoid multiple freeze/thaw cycles.

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**Important Note:** Centrifuge before opening to ensure complete recovery of vial contents.

**Catalog #:** K07102H **Lot #:** 3D11016

**Description:** Human anti Human RNP Antigen  
Human Antibody to Human RNP Antigen

**Specificity:** Shows only the RNP precipitate band when tested using double immunodiffusion against rabbit thymus extract. Specificity is verified by identity of precipitation with CDC-AF reference serum. The titer obtained will vary with the test system; however, undiluted antibody shows a strong RNP precipitate band in double diffusion. No reactivity at a dilution of 1:100 when tested against purified SSA, SSB, Scl-70, Sm, and Jo-1 antigens in an ELISA system designed to detect all IgG subclasses.

**Source:** Human Plasma

**Format:** Purified, Lyophilized  
Reconstitute with 2 mL of deionized water.

**Purification:** Single donor human plasma is delipidized and defibrinated. An immunoglobulin fraction is precipitated and collected.

**Concentration:** Not Determined

**Buffer:** Lyophilized from 0.01 M Phosphate, 0.13 M Sodium Chloride, pH 7.2.

**Preservative:** 0.02% Sodium Azide (prior to lyophilization).

**Applications:** Suitable for use in double immunodiffusion and ELISA. Each laboratory should determine an optimum working titer for use in its particular application. Other applications have not been tested but use in such assays should not necessarily be excluded.

**Storage:** Store at  $\leq 0^{\circ}\text{C}$ . Avoid multiple freeze/thaw cycles.

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**Important Note:** Centrifuge before opening to ensure complete recovery of vial contents.

**Catalog #:** K07105H **Lot #:** 5A02617

**Description:** Human anti Human Scl-70 Ag  
Human Antibody to Human Scl-70 Antigen

**Specificity:** Specificity is verified by identity of precipitation with CDC-AF reference serum. Shows only the Scl-70 precipitate band when tested using double immunodiffusion against rabbit thymus extract. The titer obtained will vary with the test system; however, undiluted antibody shows a strong Scl-70 precipitate band. Shows no reactivity at a dilution of 1:100 when tested against purified SSA, SSB, Sm, Sm/RNp and Jo-1 antigen in an ELISA system designed to detect all IgG subclasses.

**Source:** Human Plasma

**Format:** Purified, Lyophilized  
Reconstitute with 2 mL deionized water.

**Purification:** Single donor human plasma is delipidized and defibrinated. An immunoglobulin fraction is then precipitated and collected.

**Concentration:** Not Applicable

**Buffer:** Lyophilized from 0.01 M PBS, 0.13 M Sodium Chloride, pH 7.2.

**Preservative:** 0.02% Sodium Azide (prior to lyophilization).

**Application:** Suitable for use in Immunodiffusion and ELISA. Each laboratory should determine an optimum working titer for use in its particular application. Other applications have not been tested but use in such assays should not necessarily be excluded.

**Storage:** Store at  $\leq 0^{\circ}\text{C}$ . Avoid multiple/freeze thaw cycles.

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**Important Note:** Centrifuge before opening to ensure complete recovery of vial contents.

**Catalog #:** K07101H **Lot #:** 1I25622

**Description:** Human anti Human Jo-1 Antigen  
Human Antibody to Human Jo-1 Antigen

**Specificity:** Specificity is verified by identity of precipitation with CDC-AF reference serum. Shows no reactivity at a dilution of 1:100 when tested against purified SSA, Sm/RNP, Scl-70, SSB, and Sm antigens in an ELISA system designed to detect all antibody classes. Shows only the Jo-1 precipitate band when tested using double immunodiffusion against rabbit thymus extract. The titer obtained will vary with the test system; however, undiluted antibody shows a strong Jo-1 precipitate band.

**Source:** Human Plasma

**Format:** Purified, Lyophilized  
Reconstitute with 2 mL deionized water.

**Purification:** Single donor human plasma is delipidized and defibrinated. An immunoglobulin fraction is then precipitated and collected.

**Concentration:** Not Applicable

**Buffer:** Lyophilized from 0.01 M PBS, 0.13 M Sodium Chloride, pH 7.2.

**Preservative:** 0.02% Sodium Azide (prior to lyophilization).

**Application:** Suitable for use in Immunodiffusion and ELISA. Each laboratory should determine an optimum working titer for use in its particular application. Other applications have not been tested but use in such assays should not necessarily be excluded.

**Storage:** Store at  $\leq 0^{\circ}\text{C}$ . Avoid multiple/freeze thaw cycles.

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