Erythropoietin

Atellica IM Analyzer and ADVIA Centaur Systems

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Erythropoietin (EPO) is a hormone that is essential for the production of red blood cells (RBCs), which carry oxygen from the lungs to the rest of the body. Erythropoietin (EPO) is used primarily to help diagnose the cause of anemia. Sometimes it is used to help diagnose the cause of too many red blood cells (polycythemia or erythorocytosis) or as part of an evaluation of a bone marrow disorder.[1]

A failure to produce sufficient EPO accounts for the moderate to severe anemias observed in end-stage renal disease. Decreased EPO production is attributed to the destruction of renal production sites.[2,3]

Examples of anemias in which EPO levels are elevated include iron deficiency anemia, reduction of blood flow to the kidney (as in blood loss), and hemoglobinopathies, which exhibit an increased affinity of hemoglobin for oxygen.[4]

Measurement of EPO is useful in distinguishing primary from secondary polycythemia. In polycythemia vera (PV), the most common type of primary polycythemia, EPO levels are diminished but erythropoiesis occurs independent of stimulation by EPO.[2] Secondary polycythemia is characterized by elevated EPO levels in response to conditions causing hypoxia. Secondary polycythemia may be caused by a variety of factors, including defective hemoglobin, smoking, pulmonary fibrosis, cardiac disease, and tumors.[4,5] Both types of polycythemia result in increased red blood cell mass.

The Siemens Healthineers EPO assay offered on the ADVIA Centaur® XP/XPT/CP Immunoassay Systems and the Atellica® IM Analyzer uses state-of-the-art, patented acridinium ester (NSP-DMAE) technology with low nonspecific binding, allowing for excellent sensitivity.

EPO Assay Benefits

- Achieve accurate diagnosis with excellent sensitivity and low-end precision compared to other commercially available EPO assays.
- Increase lab efficiency and cost-effectiveness by avoiding send-outs and alternate platform testing.
- Enable clinicians to quickly differentiate anemia and polycythemia conditions with a broad menu on one trusted, automated platform.

For use outside of the U.S.

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Assay Characteristics[6-8]

System	Sample Type	Sample Volume	LoB	LoD	LoQ	Assay Range	Calibration Interval	Onboard Stability	Time to First Result
Atellica IM Analyzer	Serum, plasma (dipotassium EDTA, lithium heparin, sodium heparin)	100 µL	0.69 mIU/mL	0.98 mIU/mL	0.98 mIU/mL	0.98–750.00 mIU/mL	Lot: 28 days Pack: 14 days	28 days	19 min
ADVIA Centaur XP/XPT Systems	Serum, plasma (dipotassium EDTA, lithium heparin, sodium heparin)	100 µL	0.46 mIU/mL	0.75 mIU/mL	0.83 mIU/mL	0.83–750.00 mIU/mL	14 days	28 days	57 min
ADVIA Centaur CP System	Serum, plasma (dipotassium EDTA, lithium heparin, sodium heparin)	100 µL	0.66 mIU/mL	0.89 mIU/mL	0.89 mIU/mL	0.89–750.00 mIU/mL	14 days	28 days	53 min

Method Comparison Data[6-8]

System	Specimen	Comparative Platform	Regression Equation	Sample Interval	n	r
Atellica IM Analyzer	Serum	ADVIA Centaur XP EPO	y = 0.94x + 0.58 mIU/mL	3.92–682.96 mIU/mL	119	1.00
ADVIA Centaur XP System	Serum	Beckman ACCESS EPO	y = 0.99x + 0.36 mIU/mL	4.17–535.82 mIU/mL	122	1.00
ADVIA Centaur CP System	Serum	ADVIA Centaur XP EPO	y = 1.02x + 0.02 mIU/mL	4.70–566.70 mIU/mL	145	1.00

Standardization[6–8]

The ADVIA Centaur and Atellica IM EPO assays are traceable to the World Health Organization (WHO) 2nd International Reference Preparation for Erythropoietin (Human, urinary derived); NIBSC code 67/343. Assigned values for calibrators are traceable to this standard. The ADVIA Centaur and Atellica IM EPO assays are also traceable to the 3rd World Health Organization (WHO) International Standard for Erythropoietin, recombinant, for bioassay; NIBSC code 11/170.

System	SMN No.	Tests per Kit	Contents/Description
Atellica IM Analyzer	10733006	100	• 1 ReadyPack® primary reagent pack containing Atellica IM EPO Lite Reagent and Solid Phase • 1 vial Atellica IM EPO low calibrator • 1 vial Atellica IM EPO high calibrator
	10733008	1 x 7.0 mL controls 1–3	Atellica IM EPO Quality Control Material
	10733007	1 x 1.0 mL controls 1–5	Atellica IM EPO Master Curve Material
ADVIA Centaur XP/XPT/CP Systems	10995096	100	• 1 ReadyPack primary reagent pack containing ADVIA Centaur EPO Lite Reagent and Solid Phase • 1 vial ADVIA Centaur EPO low calibrator • 1 vial ADVIA Centaur EPO high calibrator
	10995099	1 x 7.0 mL controls 1–3	ADVIA Centaur EPO Quality Control Material
	10995098	1 x 1.0 mL controls 1–5	ADVIA Centaur EPO Master Curve Material

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6. ADVIA Centaur XP/XPT EPO Instructions for Use: RPBL1252/R2_EN Rev. B, 2019-04
7. Atellica IM EPO Instructions for Use: RPBL1337R03_EN Rev.03, 2019-04
8. ADVIA Centaur CP EPO Instructions for Use: RPBL1433/R1_EN Rev. A, 2019-08

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Published by Siemens Healthcare Diagnostics Inc. · Order No. 30-19-14106-01-76 · 11-2019 · ©Siemens Healthcare Diagnostics Inc., 2019