21-Hydroxylase Autoantibody (21-OHAb)

ELISA

ADRENAL AUTOIMMUNITY

ASSAY CHARACTERISTICS

Qualitative

Calibration:	Single-Point Reference Preparation
Controls (Included):	2 Positive, 1 Negative

TOTAL RUNNING TIME

17 hours and 40 minutes

SPECIMEN MATRIX

Human Serum

REFERENCE RANGE

Index Value < 45: Negative

Index Value ≥ 45: Positive

PRECISION

Intra-Assay Index Value	% Agreement in DX Calls	Inter-Assay Index Value	% Agreement in DX Calls
5.4	100	6.2	100
35.5	100	40.8	89
48.6	100	51.9	95
206.9	100	66.0	100

PATIENT GROUP	NUMBER OF PATIENTS POSITIVE FOR 21-OHAB	%
Addison's Disease	18/23	78%
APS Type I	18/24	75%
APS Type II	58/61	95%
Graves' Disease	0/58	0%
Hashimoto's Thyroiditis	0/30	0%
Type 1 Diabetes	2/71	2.8%
POF (No AD or APSII)	0/3	0%
Post Tuberculosis Addison's Disease	0/5	0%
Healthy Blood Donors	2/1082	0.2%

CLINICAL SENSITIVITY & SPECIFICITY

Sensitivity	87%
Specificity	99%

ORDERING INFORMATION

KR7015 – 96 Well Kit

The KRONUS Steroid 21-Hydroxylase Autoantibody (21-OHAb) ELISA Kit is for the qualitative determination of antibodies to steroid 21-hydroxylase (21-OH) in human serum. The Steroid 21-Hydroxylase Autoantibody (21-OHAb) ELISA Kit is useful as an aid in the diagnosis of autoimmune adrenal disease, whether expressed as autoimmune Addison's disease (isolated) or Addison's disease as part of the more complex autoimmune polyglandular syndrome (APS), type I or II. The assay result is to be used in conjunction with other clinical and laboratory findings and is not a substitute for functional testing required to diagnose adrenal insufficiency.

Chronic primary adrenal insufficiency (Addison's disease) is most commonly caused by the insidious autoimmune destruction of the adrenal cortex and is characterized by the presence of adrenal cortex autoantibodies in the serum. It can occur sporadically, or in conjunction with other autoimmune endocrine diseases, which together, comprise type I and type II autoimmune polyglandular syndrome (APS).

The microsomal autoantigen steroid 21-hydroxylase (55 kilodalton) has been shown to be the primary autoantigen associated with autoimmune Addison's disease. 21-OHAbs are markers of autoimmune Addison's disease, whether it presents alone, or as part of type I or type II autoimmune polyglandular syndrome. For this reason, the measurement of 21-OHAbs is an important step in the investigation of adrenal insufficiency, and may also aid in the detection of those at risk of developing autoimmune adrenal failure in the future.

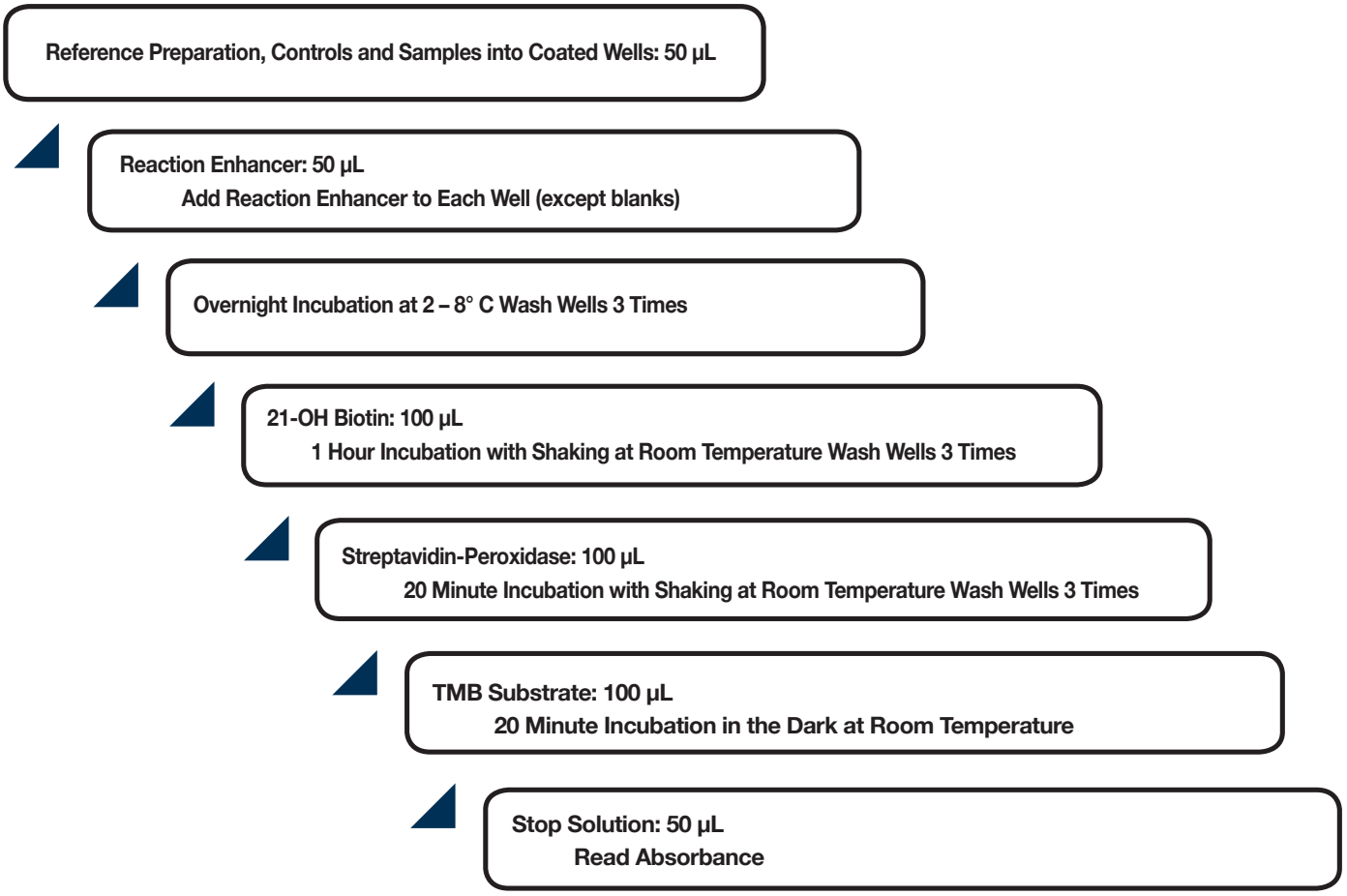
For In Vitro Diagnostic Use, Rx Only

KRONUS

800.4.KRONUS (800.457.6687) | 208.377.4800 | www.kronus.com | kronus@kronus.com

ASSAY PROCEDURE

Sample Volume: 50 µL per Well



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KRONUS …Your Source for Sensitive Autoimmune Diagnostics