



**SICKLECHECK™**  
**Rapid Immunochromatographic assay for the simultaneous detection of Hb S and Hb A**  
**in human whole blood**

**Intended Use:** \_\_\_\_\_

Sicklecheck™ a rapid, qualitative, Immunochromatographic assay for the simultaneous detection of Hb S and Hb A in human whole blood sample for diagnosis of sickle cell disorder.

**Key Points:**

<b>Utilizes monoclonal anti Hb A &amp; anti Hb S antibodies</b>	Facilitates specific detection of Hb A & Hb S
<b>Differentiate Hb A &amp; Hb S</b>	Facilitates differentiation of sickle cell trait and disease
<b>Competitive Immunochromatographic assay</b>	No risk of prozoning
<b>Excellent sensitivity and specificity</b>	Sensitivity 100% and specificity 100% compared with HPLC
<b>No interference of presence of fetal hemoglobin in sample</b>	Highly specific result for diagnosis of sickle cell disorder.
<b>10µl Whole blood sample</b>	Low specimen volume required
<b>Simple test protocol</b>	Suitable for use in field testing in limited resource setting
<b>Storage at 4°C-40°C</b>	Suitable for most climatic conditions

**Performance Validation Report Summary:****1. External Evaluation - I:**

Validated by ICMR – RMRC Bhubaneswar with 463 samples (135 Children and 328 Adult patients)

Sensitivity : 98.14%	Specificity : 99.03%
Positive predictive Value : 98.1%	Negative Predictive Value : 99.02%

**2. External Evaluation - II:**

Validated by MRU – MKCG Medical College. Berhampur (Ganjam) with 359 samples (including 22 infant samples, 5 samples with High persistence fetal hemoglobin)

	<b>Sensitivity</b>	<b>Specificity</b>
For Sickle cell disease	97.92%	100%
For Sickle cell Trait	99.07%	98.81%

**3. External Evaluation - III:**

Validated by Valsad Raktdan Kendra. Gujarat with 200 samples (112 Sickle cell trait and 27 Sickle cell disease)

	<b>Sensitivity</b>	<b>Specificity</b>
Sickle Cell disease (SCD)	100%	100%
Sickle Cell Trait (SCT)	100%	100%

**4. External Evaluation - IV:**

Validated by Phulo-Jhano Medical College & Hospital, Dumka. Jharkhand, with 235 samples (with 38 infant samples and 197 adult samples)

	<b>Sensitivity</b>	<b>Specificity</b>
Sickle Cell Disease (SS)	100%	100%
Sickle Cell Trait (AS)	100%	100%