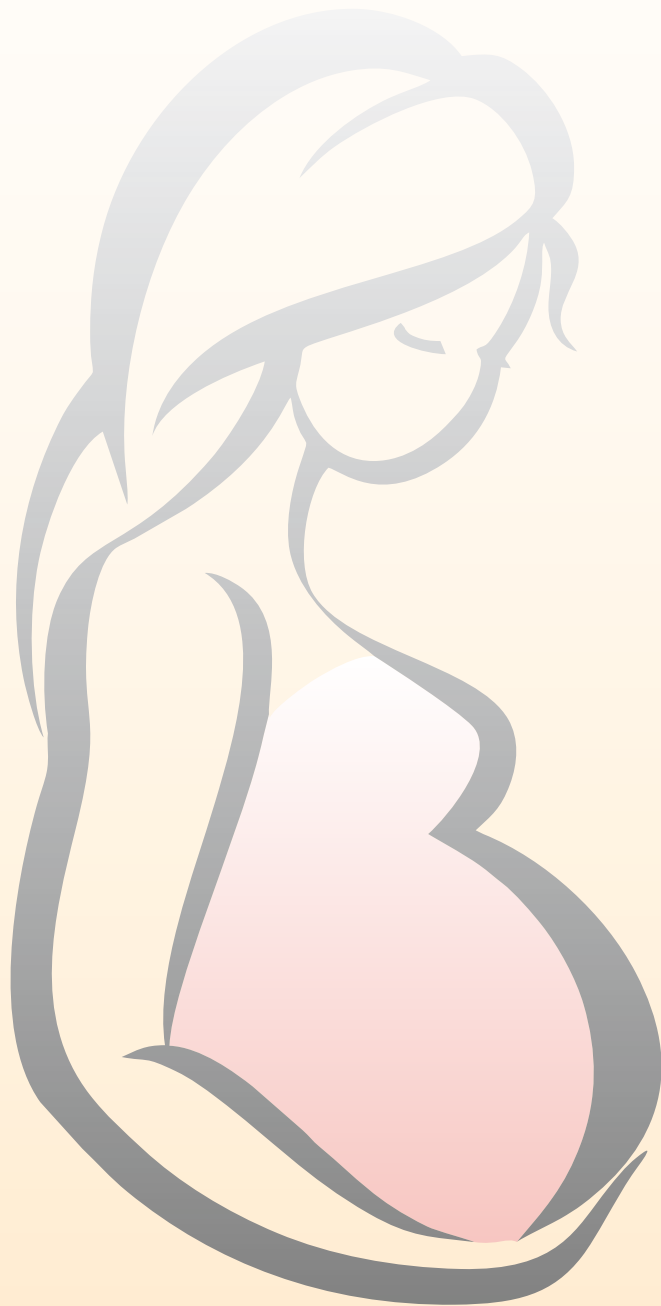


# The Art of Predicting



**Safe  
Motherhood**



• Predict • Prevent • Prevail

**PREECLAMPSIA**

# REDSPOT-PE™

## Congo Red Spot test for screening Preeclampsia

Preeclampsia (PE) affects 2-8% of pregnancies and is linked to maternal and perinatal mortality. It typically develops after the 20th week of pregnancy and is marked by high blood pressure, protein in the urine, and dysfunctions in the fetoplacental unit and multiple organs. Currently, aside from a patient's medical and pregnancy history, we have limited tools to predict which patients are at risk of preeclampsia. Accurate and early diagnosis remains a challenge, especially in resource-limited settings.

The affinity of Congo red for misfolded proteins (amyloids), known as Congophilia, is considered the gold standard for identifying amyloids. Studies have shown that misfolded proteins are present in the urine of pregnant women diagnosed with preeclampsia, often appearing well before clinical symptoms manifest.

Congo red test is an effective predictor of PE when tested in pregnant women > 20 weeks of gestation, in the absence of renal disorders, neurodegenerative disorders like Alzheimer's and Parkinson's disease or patients with other aetiologies of proteinuria.

**REDSPOT-PE™** is an **A**ffordable **R**eliable **T**est suitable for predicting or detecting preeclampsia.

### REDSPOT-PE™ Congo Red reagent

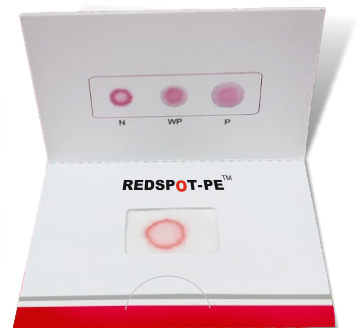
- High specificity due to High affinity for misfolded proteins
- Optimised to detect urinary Congophilia

### REDSPOT-PE™ Test card

- Standardized Cellulose membrane ensures high sensitivity for urinary Congophilia

### REDSPOT-PE™ Customised Sample reagent dropper

- Facilitates formation of prominent concentric Congo red ring in normal samples
- Helps differentiate negatives from positives



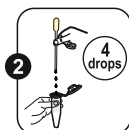
### Point of Care Test

- Suitable for on-site testing anytime anywhere
- Helps avoid unnecessary admission in obstetrical triage areas
- Ready to use reagent and test card
- Room temperature storage

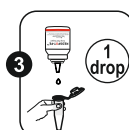
### Brief Test Procedure



Label test card and sample reagent mixing vial.



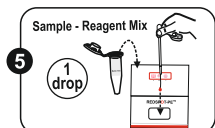
Add 4 drops of urine to sample reagent mixing vial.



Add 1 drop of Congo red reagent to the sample reagent mixing vial.



Mix well and incubate for 5 minutes at RT.



Dispense 1 drop of the mixture to the test card.



Read results at the end of 3 minutes.

### Result Interpretation

Negative



Weak Positive



Positive



\*Note: For detailed information refer IFU

### Performance: Data

Clinical Status of Samples	Status of Samples using RedSpot-PE™	
	Positive	Negative
Positive	19	3
Negative	0	94
Total Samples	116	
Sensitivity	86.36% (95%CI: 65.09% to 97.09%)	
Specificity	100.0% (95%CI: 96.15% to 100.0%)	
PPV	100.0% (95%CI: 82.35% to 100.0%)	
NPV	96.91% (95%CI: 91.63% to 98.90%)	
Accuracy	97.41% (95%CI: 92.63% to 99.46%)	

## REDSPOT-PE™ – Predicts to Prevail over Preeclampsia!

ISO 13485  
Certified Company



**TULIP DIAGNOSTICS (P) LTD.**

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