

SHAHEED HOSPITAL

DALLI RAJHARA, DIST. – BALOD C. G. 491229

**Performance evaluation of the Point of care diagnostic testing kit of REDSPOT-
PE™**

Report

Clinical Site: Shaheed Hospital, Dalhi Rajhara, Balod, Chhattisgarh - 491228

Investigators:

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Date of Report: 10th January 2025

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Abstract

This report presents an evaluation of the Pre-eclampsia diagnostic test (RDT) RedSpot-PE™. Conducted at Shaheed hospital, Balod, Chhattisgarh—the study aimed to assess the diagnostic performance, including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), of the RDT against the clinical condition of the pregnant women. More than 100 samples of pregnant women were collected by qualified technicians.

The findings confirm that the rapid test RedSpot-PE™ is reliable for the diagnosis of pre-eclampsia condition in pregnant women and can be a supporting/ screening rapid diagnostic tool in remote and resource-limited areas.

Introduction

Pre-eclampsia is a disorder of pregnancy characterized by newly onset high blood pressure and often a significant amount of protein in the urine (proteinuria). When it arises, the condition begins after 20 weeks of pregnancy. In severe cases of the disease there may be red blood cell breakdown, a low blood platelet count, impaired liver function, kidney dysfunction, swelling, shortness of breath due to fluid in the lungs, or visual disturbances. Pre-eclampsia increases the risk of undesirable outcomes for both the mother and the fetus. If left untreated, it may result in seizures at which point it is known as eclampsia¹.

Preeclampsia and related hypertensive disorders of pregnancy impact 5-8% of all births in the United States. Incidence rates for preeclampsia alone - in the United States, Canada and Western Europe, range from 2-5%². In the developing world, severe forms of pre-eclampsia and eclampsia are more common, ranging from a low of 4% of all deliveries to as high as 18% in parts of Africa. The variation in incidence rates is driven by the diversity of definitions and other criteria (including procedures, tests and their methodologies). In Latin America, pre-eclampsia is the #1 cause of maternal death. Ten million women develop pre-eclampsia each year around the world³. Worldwide about 76,000 pregnant women die each year from pre-eclampsia and related hypertensive disorders. And the number of babies who die from these disorders is thought to be on the order of 500,000 per annum. In developing countries, a woman is seven times as likely to develop preeclampsia than a woman in a developed country. From 10-25% of these cases will result in maternal death³.

Preeclampsia is a complication of pregnancy that can happen to any woman, in any pregnancy. The disease epidemiology covered in the report provides historical as well as forecasted Preeclampsia epidemiology scenario in the 7MM covering the United States, EU5 countries (Germany, Spain, Italy, France, and the United Kingdom), and Japan from 2019 to 2032⁴. In India, the incidence of preeclampsia is reported to be 8-10% among the pregnant women. According to a study, the prevalence of hypertensive disorders of pregnancy was 7.8% with preeclampsia in 5.4% of the study population in India⁵. These numbers are gradually increasing every year⁶.


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Proteinuria: Pathophysiological conditions in some diseases lead to the formation of structurally abnormal misfolded proteins. Misfolded proteins are well known for their role in the formation of amyloid plaques seen in neurodegenerative disorders like Alzheimer's disease, Parkinson's disease, Huntington's disease, Amyotrophic Lateral Sclerosis, Spongiform Encephalopathy and Familial Amyloidotic Polyneuropathy⁷. Studies have indicated that misfolded proteins appear in urine, well before the onset of clinical symptoms of Preeclampsia⁸ and hence the determination of urinary misfolded proteins facilitates for early diagnosis and risk prediction of preeclampsia.

The REDSPOT-PE test is based on the chemistry/ interaction between Congo red (CR) and amyloid proteins. Congo red (CR) is a synthetic diazo dye with specific affinity for amyloid protein⁹⁻¹¹. This special affinity of misfolded protein fibres to Congo red dye is known as congophilia. When Congo red reagent is mixed and incubated with the samples for a minute and spotted on paper, the Congo red reagent will form hydrogen bonds with cellulose of the test paper, thus slowing down its flow through the porous paper surface, creating a tight circle made by aqueous CR solutions on the test paper. If the sample contains amyloids (PE urine), then a part of CR binds proportionally with the concentration of the amyloids during the incubation time and when this sample is spotted on cellulose test paper there will be only little or no free CR available for cellulose bonding, hence the aggregates/complex of CR-amyloids spread on the test paper forming a wide diffused pink circle indicating positive for Pre-eclampsia¹². A homogeneously diffused pink circle appears if all CR is engaged with amyloids. If the middle circle like halo is still visible this means some free CR still exists available for bonding to cellulose.

Objective of the Evaluation

The primary objective of this evaluation was to assess the diagnostic performance of the RedSpot-PE™ rapid diagnostic tests (RDTs) for Pre-eclampsia conditions in pregnant women. Specifically, the study aimed to determine the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of these RDTs compared to the clinical diagnosis.

By evaluating these parameters, the study sought to establish the reliability, accuracy, and suitability of these RDTs for use in diverse epidemiological settings to help reduce the financial cost and fast screening, supporting informed decisions in the case management and control strategies.

This evaluation also intended to identify any procedural or environmental factors affecting test performance, ensuring robust and accessible diagnostic solutions in remote and resource-limited areas.

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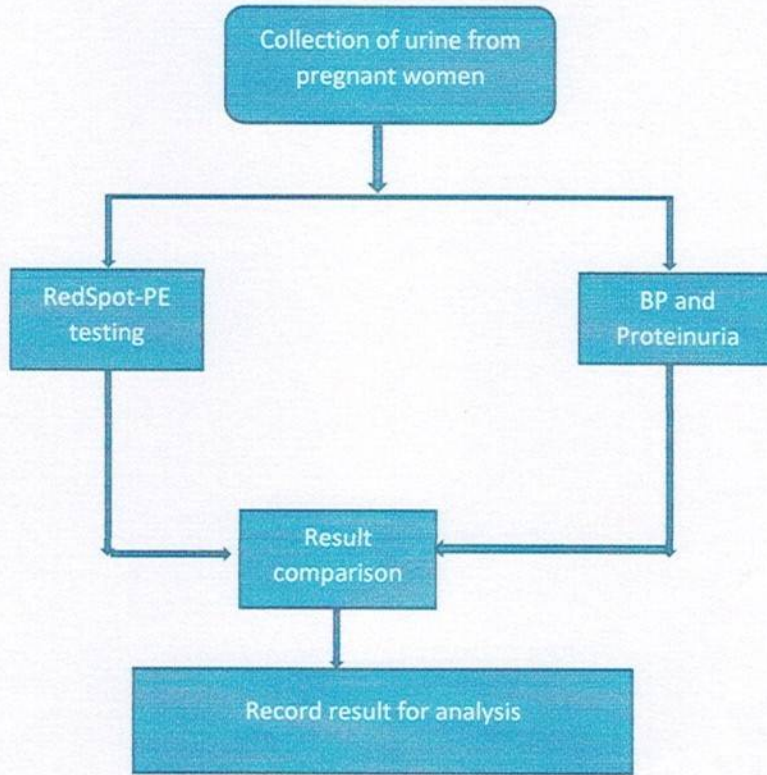
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Materials and Methods

Study Design

This is a comparative trial of a diagnostic method against the currently accepted goldstandard testing procedures, and will be conducted as shown in the flow chart:



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Study Site, Population and Sample Size

The study was conducted at Shaheed hospital, Balod, Chhattisgarh, which has a dedicated maternal and child health care wing, providing round-the-clock emergency and elective obstetric care. The health facilities conducted the test on the pregnant women who consented to the study between the period June 2024 – Nov 2024. A total of 155 samples were collected and analyzed. The pregnant women with gestational hypertension were excluded. A total of 116 samples were used for further analysis.

Collection of samples

The testing procedure involved the collection of urine samples in sterile urine container by the individual and later submitted to the medical laboratory technician.

The rapid test (RedSpot-PE™) was conducted after collection along with the Blood pressure and proteinuria measurements. The details of the individuals were entered in the respective data sheet.

Participant Recruitment Strategy

To ensure a representative sample of specimen for the evaluation of the Redspot-PE™ rapid tests, the recruitment strategy focused on selecting individuals based on the following.

1. Inclusion and Exclusion Criteria

- All pregnant women of any gestational age were considered eligible. Patients with undiagnosed medical conditions and any other underlying diseases and those with gestational hypertension were excluded.

2. Recruitment Process

- **Screening:** Potential participants were identified during routine visits to the gynecology department and inpatient admissions. Healthcare providers were briefed on the study criteria to facilitate screening and referrals.

3. Operators and Test Personnel

The evaluation study was conducted by a qualified team of operators, RDT testers, and doctors and helpers at the study site.

Statistical Analysis Method

The diagnostic performance of the RedSpot-PE™ rapid tests was evaluated using statistical analysis on MedCalc's diagnostic test evaluation calculator (https://www.medcalc.org/calc/diagnostic_test.php). This tool enabled precise calculation of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and

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accuracy, along with their respective confidence intervals.

1. Statistical Parameters Calculated

- **Sensitivity:** Calculated as the proportion of true positives (TP) among those who are truly sick, providing a measure of the test's ability to correctly identify the cases.
- **Specificity:** Calculated as the proportion of true negatives (TN) among those who are not sick, indicating the test's ability to correctly identify the negative.
- **Positive Predictive Value (PPV):** The probability that patients with a positive test result truly have Pre-eclampsia, calculated using TP and false positives (FP).
- **Negative Predictive Value (NPV):** The probability that patients with a negative test result truly do not have Pre-eclampsia, calculated using TN and false negatives (FN).
- **Accuracy:** The overall proportion of correct diagnoses (both TP and TN) among all cases tested, reflecting the test's overall reliability.

2. Confidence Intervals

- For each of the performance measures (sensitivity, specificity, PPV, NPV, and accuracy), 95% confidence intervals (CIs) were calculated to quantify the precision and reliability of the estimates. The CIs were automatically generated by the MedCalc software, using a standard approach based on the binomial distribution.

3. Software and Reporting

- MedCalc software was used due to its user-friendly diagnostic accuracy calculator, providing robust statistical calculations essential for validating the test's performance. Results were presented as percentages with 95% CIs to illustrate the precision of the estimates, aligning with clinical diagnosis.

Lots under study:

The evaluation included following batch of the RedSpot-PE™ rapid tests to ensure comprehensive assessment and consistency in performance. The specific lot used are detailed below:

RedSpot-PE™

Lot. No. : 1972405T1

Mfg. Date : 05/2024

Expiry Date : 04/2025

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Results:


S N	Sample Id	Gestational age weeks	Systolic/Diastolic BP (mmHg)	Proteinuria	Edema	Diagnosis	Test Results	Test Card
1	2023SHD23100	36	130/90	nil	nil	Normal	negative	
2	2024SHD13082	34	170/100	++	nil	PE	positive	
3	2024SHD13099	NA	90/60	trace	nil	Normal	negative	
4	2024/93069	36	110/70	nil	nil	Normal	negative	
5	2024/12989	36	160/100	trace	nil	PE	negative	
6	2024SHD3724	NA	120/80	nil	nil	Normal	negative	
7	2022SHD6907	30	120/90	nil	nil	Normal	negative	
8	2024SHD11267	NA	130/70	nil	nil	Normal	negative	
9	2024SHD11627	36	140/100	trace	nil	PE	positive	
10	20243236	28	100/60	nil	nil	Normal	negative	
11	2024SHD6386	36	80/60	nil	++	Normal	negative	
12	2024SHD9575	30	110/70	nil	nil	Normal	negative	

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S N	Sample Id	Gestational age weeks	Systolic/Diastolic BP (mmHg)	Proteinuria	Edema	Diagnosis	Test Results	Test Card
13	2024SHD4011	34	210/110	++	nil	PE	positive	
14	2024SHD2999	32	110/80	nil	nil	Normal	negative	
15	2024SHD2696 0	32	100/70	nil	nil	Normal	negative	
16	2024SHD8944	36	120/90	nil	nil	Normal	negative	
17	2022SHD6677	34	100/60	nil	nil	Normal	negative	
18	2022SHD2066	36	120/80	nil	nil	Normal	negative	
19	2024SHD2628	36	90/70	nil	nil	Normal	negative	
20	2024SHD7723	30	140/90	nil	++	PE	positive	
21	2024SHD1519 7	28	110/80	nil	nil	Normal	negative	
22	2024SHD1382 4	30	120/80	nil	nil	Normal	negative	
23	2024SHD1461 7	36	160/110	nil	nil	PE	positive	
24	2021SHD3375	36	130/80	nil	++	PE	negative	


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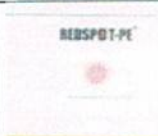

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S N	Sample Id	Gestational age weeks	Systolic/Diastolic BP (mmHg)	Proteinuria	Edema	Diagnosis	Test Results	Test Card
25	2024SHD14409	36	140/90	trace	nil	PE	positive	
26	2024SHD14345	18	140/90	nil	nil	PE	positive	
27	2024SHD11074	30	100/60	nil	nil	Normal	negative	
28	2024SHD3371	28	110/70	nil	nil	Normal	negative	
29	2024SHD5959	34	170/130	nil	++	PE	positive	
30	2024SHD14941	42	190/130	nil	nil	PE	positive	
31	2024SHD18159	36	120/90	nil	+	Normal	negative	
32	2.02E+08	NA	170/130	nil	nil	PE	positive	
33	2024SHD15170	32	120/80	nil	+	Normal	negative	
34	2024SHD10032	36	110/70	++	nil	PE	positive	
35	2024SHD3642	36	110/80	nil	nil	Normal	negative	
36	2022SHD15260	36	110/70	nil	nil	Normal	negative	

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S N	Sample Id	Gestational age weeks	Systolic/Diastolic BP (mmHg)	Proteinuria	Edema	Diagnosis	Test Results	Test Card
37	2024SHD9238	32	120/80	nil	nil	Normal	negative	
38	2022SHD6848	36	110/80	nil	nil	Normal	negative	
39	2024SHD0178 14	36	120/80	nil	nil	Normal	negative	
40	2024SHD3069	30	110/70	nil	+	Normal	negative	
41	2024SHD1368 0	20	90/70	nil	nil	Normal	negative	
42	2024SHD1780 1	36	120/90	nil	nil	Normal	negative	
43	2021SHD2565 6	34	100/70	nil	nil	Normal	negative	
44	2021SHD1243 9	34	90/60	nil	nil	Normal	negative	
45	2024SHD 13794	34	100/70	nil	nil	Normal	negative	
46	2024SHD5240	30	100/60	nil	nil	Normal	negative	
47	2021SHD2224 8	16	110/80	nil	nil	Normal	negative	


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S N	Sample Id	Gestational age weeks	Systolic/Diastolic BP (mmHg)	Proteinuria	Edema	Diagnosis	Test Results	Test Card
48	2023SHD4628	36	110/70	nil	+	Normal	negative	
49	2024SHD3371	34	110/70	nil	nil	Normal	negative	
50	2022SHD9910	20	100/70	nil	nil	Normal	negative	
51	2022SHD1753 4	24	100/60	nil	nil	Normal	negative	
52	2023SHD1972 7	30	100/80	nil	nil	Normal	negative	
53	2022SHD7920	24	110/80	nil	nil	Normal	negative	
54	2022SHD2092 5	34	110/80	nil	nil	Normal	negative	
55	2024SHD1400 1	36	160/90	nil	+++	PE	negative	
56	2024SHD2018 2	40	110/70	nil	nil	PE	positive	
57	2022SHD5234	36	140/110	+	+++	PE	positive	
58	2024SHD2062 9	36	170/110	+++	nil	PE	positive	


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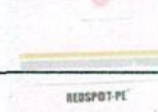
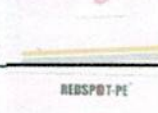

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S N	Sample Id	Gestational age weeks	Systolic/Diastolic BP (mmHg)	Proteinuria	Edema	Diagnosis	Test Results	Test Card
59	2024SHD20579	36	170/100	nil	nil	PE	weakly positive	
60	2024SHD20578	36	130/90	nil	+	PE	weakly positive	
61	2024SHD19724	36	140/90	nil	nil	PE	weakly positive	
62	2022SHD13813	36	130/80	+++	++	Normal	negative	
63	2024SHD3371	36	150/100	nil	nil	Normal	negative	
64	2022SHD13670	36	130/90	nil	nil	Normal	negative	
65	2024SHD11883	36	90/60	nil	nil	Normal	negative	
66	2024SHD6271	36	110/70	nil	nil	Normal	negative	
67	2024SHD8118	34	90/50	nil	nil	Normal	negative	
68	9024SHD5010	32	130/80	nil	nil	Normal	negative	
69	2024/19213	NA	110/70	trace	nil	Normal	negative	


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S N	Sample Id	Gestational age weeks	Systolic/Diastolic BP (mmHg)	Proteinuria	Edema	Diagnosis	Test Results	Test Card
70	2024SHD19209	38	120/90	nil	nil	Normal	negative	
71	2024SHD5531	36	130/90	nil	nil	Normal	negative	
72	2021SHD13435	30	130/90	nil	nil	Normal	negative	
73	2024SHD21574	36	130/90	nil	nil	Normal	negative	
74	2024SHD21781	26	170/120	nil	nil	PE	positive	
75	2024SHD21837	24	80/50	nil	nil	Normal	negative	
76	2024SHD21859	28	100/70	nil	nil	Normal	negative	
77	2024SHD21870	36	110/70	nil	nil	Normal	negative	
78	2024SHD21836	36	100/70	nil	nil	Normal	negative	
79	2023SHD19030	26	100/70	nil	nil	Normal	negative	
80	2024SHD9847	30	130/70	nil	nil	Normal	negative	


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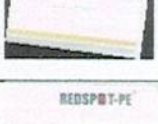





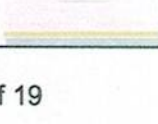
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S N	Sample Id	Gestational age weeks	Systolic/Diastolic BP (mmHg)	Proteinuria	Edema	Diagnosis	Test Results	Test Card
81	2024SHD12960	24	120/70	nil	nil	Normal	negative	
82	2024SHD12855	24	80/50	nil	nil	Normal	negative	
83	2024SHD18770	30	100/70	nil	nil	Normal	negative	
84	2024SHD18378	36	110/70	nil	nil	Normal	negative	
85	2023SHD13339	NA	110/70	nil	nil	Normal	negative	
86	2024SHD4205	34	110/70	nil	nil	Normal	negative	
87	2022SHD88	26	110/70	nil	nil	Normal	negative	
88	2024SHD1341	36	100/70	nil	nil	Normal	negative	
89	2023SHD12221	34	130/90	nil	nil	Normal	negative	
90	2021SHD2378	34	130/90	nil	nil	Normal	negative	
91	2024SHD12911	32	90/60	nil	nil	Normal	negative	
92	2024SHD12092	36	100/70	nil	nil	Normal	negative	


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S N	Sample Id	Gestational age weeks	Systolic/Diastolic BP (mmHg)	Proteinuria	Edema	Diagnosis	Test Results	Test Card
93	2024SHD11506	28	100/70	nil	nil	Normal	negative	
94	22SHD5441	28	100/70	nil	nil	Normal	negative	
95	2023SHD14715	NA	120/80	nil	nil	Normal	negative	
96	2024SHD3483	32	90/60	nil	nil	Normal	negative	
97	2024SHD21961	36	110/70	nil	nil	Normal	negative	
98	2024SHD21969	38	100/80	nil	nil	Normal	negative	
99	2024SHD4205	32	110/80	nil	nil	Normal	negative	
100	2024SHD12070	32	190/120	+	nil	PE	positive	
101	2023SHD17484	36	130/90	nil	nil	Normal	negative	
102	2024SHD15707	24	90/70	nil	nil	Normal	negative	
103	2024SHD22310	34	100/60	nil	nil	Normal	negative	
104	2024SHD16008	28	110/80	nil	nil	Normal	negative	


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S N	Sample Id	Gestational age weeks	Systolic/Diastolic BP (mmHg)	Proteinuria	Edema	Diagnosis	Test Results	Test Card
105	2024SHD11278	32	90/60	nil	nil	Normal	negative	
106	2022SHD13188	32	100/60	nil	nil	Normal	negative	
107	2024SHD15389	32	110/70	nil	nil	Normal	negative	
108	2.02E+08	24	120/70	nil	nil	Normal	negative	
109	2022SHD15162	18	90/60	nil	nil	Normal	negative	
110	2024SHD19738	38	90/60	nil	nil	Normal	negative	
111	2021SHD28973	32	100/60	nil	nil	Normal	negative	
112	2021SHD9950	30	90/70	nil	nil	Normal	negative	
113	2022SHD17132	38	100/80	nil	nil	Normal	negative	
114	2021SHD2520	34	110/80	nil	nil	Normal	negative	
115	2024SHD12920	30	90/60	nil	nil	Normal	negative	
116	2022SHD19073	NA	100/70	nil	nil	Normal	negative	


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Inference:

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%)	

Conclusion:

The kit is for early detection of Preeclampsia and Eclampsia (Preeclampsia condition) using urine samples of pregnant females. 116 urine samples were screened and compared with the known conditions of the subjects. The subject with Gestational hypertension (That is the term used for only increased blood pressure without any proteinuria or signs of any organ damage) were omitted from the present study.

Based on Interpretation of the test results, it can be concluded that the REDSPOT - PE™ kit for determination of early detection of Preeclampsia and Eclampsia using urine samples of pregnant females when tested is reliable for screening purpose, with respect to the correlation between the reference condition and tested samples.

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