

Precision Performance of the Mira Confirm Test and Comparison with the Semi-Quantitatively Product

Objective

Conduct a precision study to confirm the performance characteristics of different fertility-tracking products.

Study Design

The precision is the variability of the device when used over an indefinitely long period of time. To some degree, several sources of variability contribute to this long-term precision. The main objective of the precision evaluation experiment is to estimate the device's precision or measurement method used on a single instrument in a laboratory.

Terms Used to Describe the Time-Related Components of Precision

- Repeatability
- Between-run precision
- Within-day precision
- Between-day precision
- Within-laboratory precision

Repeatability and within-laboratory precision generate the most interest.

Definitions

Precision –The closeness of agreement between independent test/measurement results obtained under stipulated conditions. Precision also refers to how similar item measurements are to each other. For example, *between-run precision* measures result in variation between different runs of the same measurement setup (e.g., measuring day and then measuring at night). At the same time, *between-day precision* measures result in variation between days.

Repeatability – The variation of successive measurements of the same variable taken under the same conditions in a short time.

Run – An interval in which the trueness and precisions of a testing system are expected to be stable. However, it cannot be greater than 24 hours or less than the frequency recommended by the manufacturer.

Intermediate precision conditions – When testing or measurement results are obtained by the same method on identical test/measurement items in the same testing facility under different

operating conditions. Some examples include conducting the same measurement procedure, measuring system, exact location, and replicate measurements on the same or similar objects over an extended time.

NOTES:

A) There are four elements to the operating conditions: **time, calibration, operator, and equipment.**

B) The changed elements in operating conditions must be noted. For example, this could include the aforementioned “between-run” and “between-day” precision estimates. Other precision estimates include “within-device” and “within-laboratory.”

The Precision test will be simplified under this experiment as follows:

- Testing based on repeatability.
- Preparing two different concentrations of samples; testing each sample 7-9 times with other products.
- Conducting between-day precisions.
- Testing the same sample daily with different products for five consecutive days. During the testing days, each product is tested twice. The sample is prepared with 5µg/ml of Pregnantiol-3-glucuronide and diluted by artificial urine.
- Conducting between-run precisions.
- Testing the same sample with different products three different times. Furthermore, repeating the test in 5-10 minute increments.

Materials and Equipment

- Mira Confirm Test System (used to test the urinary PdG hormone).
- Mira Analyzer: E35CE926EE.
- Mira Fertility Confirm Wand: 2021120906.
- Oova product test of the urinary LH and PdG hormones.
- Oova cartridges: 1346-9242020.
- Proov product test of the urinary PdG hormone.
- Proov PdG Test: LN1516.

Procedures

1. Prepare the sample with 5µg/ml of Pregnantiol-3-glucuronide diluted by the artificial urine. Divide the 30 ml sample into five servings. Prepare a 6 ml sample with 2.5µg/ml of Pregnantiol-3-glucuronide diluted by the artificial urine.
2. Respectively test the sample with Mira, Oova, and Proov products. Test each product twice.
3. Respectively test the sample with Mira and Proov products. Test each product three times within 5 and 10-minute increments. Repeat the test later with the tested product.
4. Respectively test the 2.5 and 5µg/ml samples with Mira and Proov products. Test each product and concentration 7-9 times.
5. Repeat step number 2 for five consecutive days.

Results

Between-day precision

During the five-day tests, Mira showed the lowest variability with a CV of 11.5%, compared with Proov's CV of 37.6% and Oova's 87.8% (**Table 1**).

Table 1. The between-day precision test results of different products.

Test Day	Conducted Tests	Test Results of Products		
		Oova	Proov	Mira
1	1	0.17%	3.9	4.5
	2	0	4.8	3.8
2	1	100%	3.5	4.6
	2	0	1.5	4.2
3	1	73.68%	3.7	5.6

	2	56.27%	5.3	4.3
4	1	66.10%	7	4.3
	2	73.87%	2.5	4
5	1	63%	5.8	4.2
	2	4.34%	5.1	4
AV		43.74%	4.31	4.35
CV		87.8%	37.6%	11.5%

Between-run precision

Compared with Proov, Mira showed much lower variability with an overall CV of 3.18%, while Proov had 40.55%. Furthermore, the results illustrated that the semi-quantitative product varied during different tests with the same sample of strips or wands.

Test Time	Results of Different Products					
	Proov			Mira		
First Test	7	2.5	5.8	4.3	4	4.2
5 Mins. Later	3.6	3.1	3.3	4.4	4.2	4.4

10 Mins. Later	3.3	2.9	6.5	4.4	4.4	4.3
AV	4.63	2.83	5.20	4.37	4.20	4.30
CV	36.22%	8.80%	26.41%	1.08%	3.89%	1.90%
Overall AV	4.22			4.29		
Overall CV	40.55%			3.18%		

Repeatability

During the repeatability test, Mira showed fewer variations, with a CV of less than 17%, compared to Proov, who had more than 25%.

Product	Proov		Mira	
Concentration	2.5µg/ml	5µg/ml	2.5µg/ml	5µg/ml
Results	3.4	2.9	2.6	5.2
	3.2	2.9	2.0	5.5
	2.3	3.7	2.6	5.3
	2.1	1.9	2.1	8.0
	1.9	2.7	2.4	5.7

	1.2	3.4	2.7	6.3
	1.3	4.6	2.6	6.0
AV	2.2	3.2	2.4	6.0
CV	38.75%	26.99%	11.22%	16.43%

Conclusion

Compared to other PdG, semi-quantitative test products, Mira Confirm Test Wands maintained a higher precision performance with lower variability.

In addition, this finding illustrates that the Mira Confirm Test products can capture more subtle changes during a urinary test.

Claims

Compared with other products, the Mira Fertility Confirm product shows high precision during testing. This precision helps capture subtle changes during daily tests.

The coefficient of variation for Mira is about 20%. On the other hand, the coefficient of variation for Proov is about 30%. The difference indicates that Mira has a high precision (meaning low variation at one concentration during multiple tests). This high precision provides an overall more reliable result.

Disclaimer

According to EP5-A2 and EP10-A2, this is an internal and simplified experiment,

Accuracy refers to a measurement close to the actual or accepted value. Precision refers to how close measurements of the same item are to each other. Precision is independent of accuracy.

References

[1] Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition. NCCLS document EP5-A2 [ISBN 1-56238-542-9]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

[2] Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline—Second Edition. NCCLS document EP10-A2 [ISBN 1-56238-482-1]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.