

PROGENSA™ PCA3/PSA Proficiency Panels

Not for *in vitro* diagnostic use.

For U.S. export only.

These reagents must not be substituted for the mandatory calibrator reagents provided with the PROGENSA PCA3 assay kits.

Intended Use

The PROGENSA PCA3/PSA Proficiency Panel is to be used for training and assessing proficiency in laboratory testing procedures. The panel is formulated for use with the PROGENSA™ PCA3 Assay and no other prostate cancer assay.

Summary and Explanation of the Test

Establishing and monitoring operator performance in diagnostic test procedures is a key component of laboratory training and quality assurance programs. Proper use of test panels can assist laboratories in improving the quality and proficiency of routine testing. This single use panel is labeled for use in a masked fashion, as deemed appropriate by laboratory management.

Principles of the Procedure

The PROGENSA PCA3/PSA Proficiency Panel has been designed for use with the PROGENSA PCA3 Assay for the purpose of assessing operator proficiency. The expected result for each vial in the proficiency panel is shown in the *Expected Results* section. All proficiency panel vials contain a buffered solution containing < 5% detergent, which has been spiked to a predetermined concentration with nucleic acid transcripts. Although the PROGENSA PCA3/PSA Proficiency Panels **do not have assigned RNA copy levels**, each vial is designed to reproducibly yield a specific result (PCA3 Score) when tested in the PROGENSA PCA3 Assay. Proficiency panel vials should be analyzed in the same manner as unknown samples, according to the instructions in the PROGENSA PCA3 Assay package insert.

Reagents

PROGENSA PCA3/PSA Proficiency Panels, Cat. No. 302350

Component	Quantity	Description
Proficiency Panel Vial	8 x 2.8 mL	<i>Phosphate buffered solution containing <5% lithium lauryl sulfate, a PCA3 transcript, and a PSA transcript.</i>

Precautions

- A. Not for *in vitro* diagnostic use.
- B. Each proficiency panel vial is designed for a single use. Excess material in each vial is to be appropriately discarded.
- C. Use Standard Precautions; treat every sample as potentially infectious. Do not pipette by mouth; do not eat, drink, or smoke in the laboratory work area. Wear disposable gloves and laboratory coats when handling proficiency panel vials. Wash hands thoroughly after handling proficiency panel vials.
- D. Avoid microbial and ribonuclease contamination of proficiency panel vials. Use of filtered, disposable pipette tips is strongly recommended.

Storage Instructions

Proficiency panel vials are stable when stored unopened at 2°C to 8°C until the expiration date. Do not use after the expiration date.

Reagent Preparation

Mix proficiency panel vials thoroughly by gentle inversion. Do not vortex as this can cause excessive foaming. Treat proficiency panel vials as test specimens, following the procedures from the PROGENSA PCA3 Assay package insert.

Procedure

PROGENSA PCA3/PSA Proficiency Panels may be used with any PROGENSA PCA3 assay kit reagents.

The PROGENSA PCA3/PSA Proficiency Panels are for use with the PROGENSA PCA3 Assay. For testing protocols, refer to the PROGENSA PCA3 Assay package insert.

Instructions for Use

PROGENSA PCA3/PSA Proficiency Panel vials are provided as single use vials. Each vial contains sufficient volume to test for both the PCA3 and PSA analytes. These vials may be included as test specimens in a PROGENSA PCA3 Assay run according to the PROGENSA PCA3 Assay package insert.

Quality Control

Since the PROGENSA PCA3/PSA Proficiency Panels do not have assigned RNA copy levels, it is recommended that each laboratory ensure that the expected results (PCA3 Scores - see *Expected Results* section) for the PROGENSA PCA3/PSA Proficiency Panel are obtained prior to routine testing. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory.

Expected Results

Results are given as a ratio of the two analytes (PCA3 Score) and are calculated as follows:

$$\text{PCA3 Score} = [\text{PCA3 copies/mL} / \text{PSA copies/mL}] \times 1000$$

The expected results when tested in the PROGENSA PCA3 Assay are as follows:

Proficiency Panel Vial	Expected PCA3 Score
A	<25
B	<50
C	>75
D	>75
E	<25
F	<50
G	>75
H	>75

Failure to achieve the expected results listed above may be an indication of unsatisfactory test performance. Possible sources of error

include operator error, faulty performance of equipment, or contamination of reagents.

Limitations

The PROGENSA PCA3/PSA Proficiency Panel must not be substituted for the mandatory calibrator reagents provided with the PROGENSA PCA3 Assay.

Assays must be performed, and results interpreted, according to the instructions provided in the PROGENSA PCA3 Assay package insert. Deviations from these procedures may produce unreliable results.

The PROGENSA PCA3/PSA Proficiency Panel is provided for training purposes and must not be used for calibration or as a primary reference preparation in any test procedure. Adverse shipping and/or storage conditions or use of outdated panel vials and/or reagents may produce erroneous results.

Specific Performance Characteristics

The PROGENSA PCA3/PSA Proficiency Panel has been extensively tested and found to reproducibly yield the expected results (PCA3 Scores - see *Expected Results* section) when tested in the PROGENSA PCA3 Assay. Performance characteristics of the PROGENSA PCA3/PSA Proficiency Panel in assays other than the PROGENSA PCA3 Assay have not been established.

The PROGENSA PCA3/PSA Proficiency Panel has been designed to produce the expected results when used in the proper manner with the PROGENSA PCA3 Assay following procedures supplied in the PROGENSA PCA3 Assay package insert for testing unknown samples.



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