



ACCURUN[®] 644

Cystic Fibrosis
40+4 Product

About this package insert

Thank you for your interest in this ACCURUN product.

This package insert consists of two pages.

The first page contains the product name, the SeraCare logo, and contact information.

The second page contains the complete package insert text.

If the package insert you view or print does not contain two pages, or if you experience any problems, please email us at info@seracare.com, or call us at 508.244.6400.

A printed package insert will be sent to you upon request.



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THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

NAME AND INTENDED USE

ACCURUN products are intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. ACCURUN® 644 Cystic Fibrosis 40+4 Product is a synthetic multiplex product formulated for research use in molecular screening, mutation testing and assays that identify mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. *For Research Use Only. Not for use in diagnostic procedures.*

SUMMARY

A well designed quality control program can provide added confidence in the reliability of results obtained for unknown specimens. The use of independent reference products may provide valuable information concerning assay sensitivity.

PRINCIPLES OF THE PROCEDURE

ACCURUN 644 Cystic Fibrosis 40+4 Product contains synthetic reference nucleic acids comprising 47 mutations in the CFTR gene. The product is a ready to use synthetic oligonucleotides formulation. All template mutations were confirmed by sequencing.

REAGENTS

Item No. 2040-0015 1 vial, 100 µL per vial

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.

Safety Precautions

ACCURUN 644 does not contain ingredients that are considered hazardous or infectious. However, it is always advisable to use universal precautions when handling laboratory reagents. Do not pipette by mouth; do not smoke, eat or drink in areas where specimens are being handled.

Handling Precautions

Do not use ACCURUN products beyond the expiration date. Avoid contamination of the product when opening and closing the vials.

STORAGE INSTRUCTIONS

ACCURUN 644 should be stored at -20°C or colder. Once thawed and opened, ACCURUN 644 should be stored refrigerated at 2-8°C and discarded after 30 days. To prevent leakage, store vials upright.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Alterations in physical appearance may indicate instability or deterioration of ACCURUN products. Solutions that are visibly turbid should be discarded.

PROCEDURE

Materials Provided

ACCURUN 644 Cystic Fibrosis 40+4 Product contains synthetic reference nucleic acids comprising 47 mutations in the CFTR gene in molecular grade water.

Materials Required but not Provided

Refer to instructions supplied by manufacturers of the assays to be used.

Instructions for Use

Allow the product to come to room temperature before use. **Briefly spin the vials before opening.**

Quality Control

Since ACCURUN products do not have assigned values, it is recommended that each laboratory validate the use of each lot of ACCURUN with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

ACCURUN 644 Cystic Fibrosis 40+4 Product contains the mutations summarized in Table 1. Examination of raw data and allelic ratios for each mutation contained in the product may be necessary in order to get a complete understanding of the performance of the assay using the ACCURUN 644 Cystic Fibrosis 40+4 Product, as some mutations may be occluded from calls by software algorithms due to known potential interference of sequentially close mutations. (No calls) do not necessarily indicate test run failure when using synthetic reference nucleic acids. Raw data and allelic ratios will give a more complete indication of assay and product performance. When results for ACCURUN 644 Cystic Fibrosis 40+4 Product are not concordant with the data in Table 1, it may be an indication of unsatisfactory test performance. Possible sources of error include: deterioration of test kit reagents, operator error, faulty performance of equipment, or contamination of reagents.

LIMITATIONS OF THE PROCEDURE

ACCURUN PRODUCTS MUST NOT BE SUBSTITUTED FOR THE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS. TEST PROCEDURES and INTERPRETATION OF RESULTS provided by manufacturers of test kits must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. ACCURUN products are not calibrators and should not be used for assay calibration. Adverse shipping and storage conditions or use of outdated products may produce erroneous results.

EXPECTED RESULTS

ACCURUN 644 Cystic Fibrosis 40+4 Product was tested and contains synthetic reference nucleic acids comprising 47 mutations in the CFTR gene. Table 1 lists the mutations contained in ACCURUN 644 Cystic Fibrosis 40+4 Product.

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN products are designed for use with laboratory tests for purposes of monitoring assay performance. ACCURUN 644 Cystic Fibrosis 40+4 Product is manufactured with synthetic oligonucleotides comprising 47 mutations in the CFTR gene, and formulated in molecular grade water. ACCURUN products do not have assigned values. Ability to detect specific mutations will vary among different manufacturers' assays.

This product is manufactured and distributed under an agreement with Molecular Controls, using their methods for design, synthesis, and propagation of reference nucleic acids. Patent #7,425,413

Table 1: ACCURUN 644 Cystic Fibrosis 40+4 Product Mutation List.

G85E	V520F	2307insA	W1282X
394delTT	1717-1G>A	2789+5G>A	N1303K
R117H	G542X	3120+1G>A	
Y122X	S549N	Y1092C>G	Variants
621+1G>T	S549R (T>G)	Y1092C>A	5T
711+1G>T	G551D	M1101K	7T
1078delT	R553X	R1162X	9T
R334W	A559T	3659delC	I507V
R347P	R560T	S1255X(exon19)	I506V
R347H	1898+1G>A	S1255X(exon20)	F508C
A455E	1898+5G>T	3849+10kbC>T	
ΔI507	2183AA>G	3876delA	
ΔF508	2184delA	3905insT	

For assistance, contact SeraCare Technical Support at 508.244.6400.