Applied Biosystems® *TrueScience*™ Aneuploidy STR Kits

Note: For safety and biohazard guidelines, refer to the "Safety" section in the *Applied Biosystems® TrueScience™ Aneuploidy STR Kits Protocol* (PN 4454039). For warnings and precautions, refer to the *Applied Biosystems® TrueScience™ Aneuploidy STR Kits Product Insert* (PN 4453329). For every chemical, read the Safety Data Sheet (SDS) and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves. For more information on *TrueScience*™ Aneuploidy STR Kits, go to: **www.appliedbiosystems.com/aneuploidy**

This quick reference card covers:

Intended use

Kit	Intended Use
STR Plus	For the routine *in vitro* quantitative diagnosis of the three most common viable autosomal trisomies: trisomy 13 (Patau syndrome), trisomy 18 (Edwards syndrome) and trisomy 21 (Down syndrome). The kit also includes X and Y chromosome markers and the TAF9L marker for the determination of sex status.
STR-XY	For routine *in vitro* quantitative diagnosis for the analysis of sex chromosome status, including the common aneuploidies of Klinefelter syndrome and Turner syndrome.
STR-13 STR-18 STR-21	Supplemental kits containing additional autosomal markers, to be used in conjunction with STR-Plus, for the routine quantitative *in vitro* diagnosis of the three most common viable autosomal trisomies: trisomy 13 (Patau syndrome), trisomy 18 (Edwards syndrome), and trisomy 21 (Down syndrome).

The method employed by the *TrueScience*™ Aneuploidy kits is the Qf-PCR (Quantitative fluorescence-Polymerase Chain Reaction) technique.

The *TrueScience*™ Aneuploidy kits are intended to be used on DNA extracted from either chorionic villus (CV) samples or amniotic fluid (AF) samples.

The intended target population is pregnant women who have been assessed as being at "high risk" of carrying an affected fetus, by either biochemical or ultrasound diagnostic procedures, or assessed to be "at risk" due to either previous family history or maternal age.

The device is intended to be used in conjunction with other diagnostic procedures to support or discount the proposed clinical diagnosis.

The device is for Professional Use Only within a molecular or cytogenetics laboratory environment.

Kits

REF	Kit	Σ
4453756	*TrueScience*™ Aneuploidy STR-Plus	50
4453757	*TrueScience*™ Aneuploidy STR-Plus	10
4453601	*TrueScience*™ Aneuploidy STR-XY	50
4453755	*TrueScience*™ Aneuploidy STR-XY	10
4453758	*TrueScience*™ Aneuploidy STR-21	10
4453759	*TrueScience*™ Aneuploidy STR-18	10
4453760	*TrueScience*™ Aneuploidy STR-13	10

Obtain support

For the latest services and support information for all locations, go to **www.appliedbiosystems.com**, then click the link for **Support**, or contact your local Life Technologies representative.

Procedure

1	**Before you begin: one-time procedures**	Before using the *TrueScience*™ Aneuploidy Kits, set up your genetic analyzer for fragment analysis following your laboratory protocol.
2	**Before each run**	**a.** Collect samples. Use Chorionic Villus (CV) or Amniotic Fluid (AF) samples. **b.** Extract DNA. We recommend performing aneuploidy analysis with an aliquot of the cell suspension that contains sufficient cells for extraction of 1.25 to 10 ng of DNA per test.
3	**Amplify DNA**	**a.** Thaw Reaction Mix and centrifuge at 12,000 x *g* for 10 seconds. **b.** Combine 2.5 µL DNA (neg. controls: 2.5 µL water) + 10 µL Reaction Mix. **c.** Centrifuge briefly. **d.** Set thermal cycler for: 15:00 at 95°C, 26 cycles x [00:30 at 95°C, 1:30 at 59°C, 01:30 at 72°C], 30:00 at 72°C, and hold at 4°C. **e.** Run PCR.
4	**Perform capillary electrophoresis**	Set up and perform fragment analysis on your genetic analyzer according to your laboratory protocol.
5	**Analyze and interpret data**	Perform complete analysis of chromosome copy number status by comparing peak area ratios. Assess peak ratios A1/A2, where A1 is the peak area of the shorter fragment and A2 is the peak area of the longer fragment. The resulting ratio is diagnostic of locus copy number. We recommend that each laboratory develop its own interpretation and reporting procedures and criteria. Best practice guidelines for QF-PCR have been documented by the UK's Clinical Molecular Genetics Society and Association of Clinical Cytogeneticists and are available for reference at: **www.cmgs.org.uk**

Overview

The method employed by *TrueScience*™ Aneuploidy Kits uses the Quantitative fluorescence-Polymerase Chain Reaction (Qf-PCR) technique. Using PCR amplification, fluorescent dye labeled primers target highly polymorphic regions of DNA sequence called short tandem repeats (STRs) that are located on the chromosomes of interest. Each targeted STR marker is specific to the chromosome on which it is located, thus the copy number of the STR marker can be diagnostic of the copy number of the chromosome. Informative STR markers have been selected that exhibit a high heterogeneity so that copy number can be easily determined.

Disclaimer

The results obtained from these or any other diagnostic kits should be used and interpreted only in the context of the overall clinical picture. Life Technologies cannot accept responsibility for any clinical decisions that are made.

Life Technologies does not represent this guide as a comprehensive summary of all possible outcomes from using the Applied Biosystems® *TrueScience*™ Aneuploidy STR Kits. This guide is intended for use solely as an aid to memory. It is not for use in any clinical interpretation of the results of the assay. Laboratories must interpret the results of the assay in accordance with their own locally developed procedures. The UK's ACC/CMGS QF - PCR Best Practice Guidelines makes recommendations regarding the interpretation of results obtained.

This test is designed to detect specific chromosomal trisomies and sex chromosome aneuploidies as detailed in the instructions for use. It may not detect structural rearrangements involving the chromosomes tested and will not detect abnormalities in any other chromosomes. Mosaicism for the chromosomes tested may not be detected. An aneuploidy test result can only be directly applied to the tissue tested and may not represent the fetal karyotype. Maternal cell contamination (MCC) and confined placental mosaicism (CPM) may result in discrepancies between the Aneuploidy STR results and karyotype results.

Heterozygosities of the markers used in this kit were derived from a random set of samples submitted for routine analysis from a predominantly Northern European Caucasian population. Any calculations using these heterozygosities strictly apply only to the population from which the samples were taken. A small study using locally derived samples may be carried out as part of a validation study to establish heterozygosities in the population to be tested. It is not expected that population variation will significantly alter the overall informativeness of the assay.

Symbols used on labels and packaging:

IVD *IN VITRO* DIAGNOSTIC MEDICAL DEVICE

MANUFACTURER

Manufacturer's name and the address.

CONSULT INSTRUCTIONS FOR USE

USE BY

Do not use after the year, month, or day shown.

-25 °C -15 °C UPPER AND LOWER LIMITS OF TEMPERATURE

CAUTION

There are specific warnings or precautions associated with the device that are not found on the label. Consult the user documentation for further information.

CONTAINS SUFFICIENT FOR <n>TESTS

LOT BATCH CODE

Manufacturer's batch code, lot number, or batch number

REF CATALOGUE NUMBER

Manufacturer's catalogue number.

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TrueScience™ Aneuploidy Kits are manufactured for Life Technologies, UK and also manufactured as Elucigene® QST*R® kits by Gen Probe Life Sciences, UK within quality systems accredited to ISO9001:2008 and ISO13485:2003

NOTICE TO PURCHASER: Not for sale in U.S.A.

These products are sold for use by the end-user only and may not be re-sold, distributed or re-packaged.

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THE *TRUESCIENCE*™ ANEUPLOIDY KIT IS SUPPLIED FOR PROFESSIONAL *IN VITRO* DIAGNOSTIC TESTING. THIS PRODUCT DOES NOT PROVIDE A LICENSE TO PERFORM PCR UNDER PATENTS OWNED BY ANY THIRD PARTY INCLUDING HOFFMAN-LA ROCHE (HOFFMANN-LA ROCHE LTD, DIAGNOSTICS, CH-4070 BASEL, SWITZERLAND) AND ROCHE MOLECULAR SYSTEMS, INC (ROCHE MOLECULAR SYSTEMS, INC., 1145 ATLANTIC AVENUE, ALAMEDA, CALIFORNIA 94501)

Customer is responsible for any validation and compliance with regulatory requirements that pertain to their procedures.

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Technical Resources and Support
For the latest technical resources and support information for all locations, please refer to our Web site at
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