Dvysr®

Devyser Resolution 21 v2 RUO

Art. No.: 8-A012.2-21RUO

Devyser Resolution 18 v2 RUO

Art. No.: 8-A012.2-18RUO

Devyser Resolution 13 v2 RUO

Art. No.: 8-A012.2-13 RUO

Devyser Resolution XY v2 RUO

Art. No.: 8-A012.2-XY RUO

For Research Use Only

Handbook

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1. INTRODUCTION TO DEVYSER RESOLUTION V2 RUO

Intended Use

The Devyser Resolution 21 v2 RUO kit enables determination of aneuploidy in chromosome 21.
The Devyser Resolution 18 v2 RUO kit enables determination of aneuploidy in chromosome 18.
The Devyser Resolution 13 v2 RUO kit enables determination of aneuploidy in chromosome 13.
The Devyser Resolution XY v2 RUO kit enables determination of aneuploidy in chromosomes X and Y.

For research use only, not for use in diagnostic procedures.

Included in the Kit

The Devyser Resolution v2 RUO kits contain ready-to-use reagents for PCR amplification of genetic markers.

Test Procedure

DNA extraction: The Devyser Resolution v2 RUO kits can be used with QIAamp DNA Blood Mini Kit (Qiagen, cat#51104) for extraction of DNA from human whole blood and amniotic fluid (AF); QIAamp DNA Mini Kit (Qiagen, cat# 51304) for extraction of DNA from solid tissue.

Amplification: The Devyser Resolution v2 RUO kits can be used with Life Technologies/ABI GeneAmp® System 9700.

Detection: Life Technologies/Applied Biosystems Genetic Analyzers (ABI 310, 3100, 3130, 3500, 3730) that support detection of Devyser Dye Set DEV-5.

Principle of the Procedure

Quantitative fluorescent PCR (QF-PCR) analysis includes amplification, detection and analysis of short tandem repeat (STR) markers and non-polymorphic markers. Fluorescently labelled primers are used for amplification of chromosome specific markers and thus the copy number of each marker is indicative of the copy number of the chromosome.

The resulting PCR products are separated and analyzed using an automated genetic analyzer. The relative amount of each allele is quantified by calculating the ratio of the peak heights or peak areas. A normal diploid sample has the contribution of two of each of the somatic chromosomes. Two alleles of a chromosome specific STR marker are detected as two peaks in a 1:1 ratio when the marker is heterozygous and as one peak when the marker is homozygous. The detection of an additional allele as three peaks in a 1:1:1 ratio or as two peaks in a 2:1/1:2 ratio indicates the presence of an additional STR sequence possibly corresponding to an additional chromosome, as in the case of trisomy.

2. WARNINGS AND PRECAUTIONS

A.

The Devyser Resolution 21, 18, 13 and XY v2 RUO kits are for use with a total PCR reaction volume of 25 µL. Changing the reaction volume will compromise the kit performance.

B.

Avoid microbial contamination of reagents when removing aliquots from reagent vials. The use of sterile disposable aerosol barrier pipette tips is recommended.

C.

Do not pool reagents from different lots or from different vials of the same lot.

D.

Do not use a kit after its expiry date.

E.

Do not use opened or damaged kit reagent vials.

F.

Work flow in the laboratory should proceed in a unidirectional manner, beginning in the reagent pre-paration area and moving to the DNA extraction area and then to the amplification area and finally to the detection area. Pre-amplification activities should begin with reagent preparation and proceed to DNA extraction. Reagent preparation activities and DNA extraction activities should be performed in separate areas. Supplies and equipment should be dedicated to each activity and not used for other activities or moved between areas. Gloves should be worn in each area and should be changed before leaving that area. Equipment and supplies used for reagent preparation should not be used for DNA extraction activities or for pipetting or processing amplified DNA or other sources of target DNA. Amplification and detection supplies and equipment should remain in the amplification and detection area at all times.

G.

Handling of kit components and samples, their use, storage and disposal should be in accordance with the procedures defined by national biohazard safety guidelines or regulations.

H.

Wear powder free disposable gloves, laboratory coats and eye protection when handling specimens and kit reagents. Wash hands thoroughly after handling specimens and kit reagents.

3. SYMBOLS USED ON LABELS

Lot or batch number

Expiry date

Number of tests

Store below temperature shown

Catalogue number

Manufacturer

Research Use Only

4. REQUIRED MATERIAL

4.1 Included in the Kits

Configurations

The Devyser Resolution 21, 18, 13 and XY v2 RUO kits contain reagents for analysis of 25 samples each.

Components Devyser Resolution 21 v2 RUO

Cap Colour	Tube Colour	Label	Art.Nr.	Kit content
Orange	Clear	PCR Activator RUO	4-A035	1
Yellow	Amber	Resolution 21 v2 RUO	4-A207	1

Components Devyser Resolution 18 v2 RUO

Cap Colour	Tube Colour	Label	Art.Nr.	Kit content
Orange	Clear	PCR Activator RUO	4-A035	1
White	Amber	Resolution 18 v2 RUO	4-A206	1

Components Devyser Resolution 13 v2 RUO

Cap Colour	Tube Colour	Label	Art.Nr.	Kit content
Orange	Clear	PCR Activator RUO	4-A035	1
Orange	Amber	Resolution 13 v2 RUO	4-A205	1

Components Devyser Resolution XY v2 RUO

Cap Colour	Tube Colour	Label	Art.Nr.	Kit content
Orange	Clear	PCR Activator RUO	4-A035	1
Red	Amber	Resolution XY v2 RUO	4-A208	1

4. 2 Required but not Provided

Reagent Preparation

· Consumables for the Thermal Cycler
· Micropipette/dispenser with aerosol barrier tips or displacement tips

· Disposable protective gloves (powder free)

DNA Extraction

· Reagents and equipment according to manufacturer instructions for use

· Micropipette/multipipette with aerosol barrier tips

Amplification

· Thermal Cycler: Life Technologies/ABI GeneAmp® PCR System 9700 using 9600 mode. For use of alternative thermal cyclers the following ramping rates must be applied: heating 0,8 ˚C/s, cooling 1,6 ˚C/s
· Micropipette/dispenser with aerosol barrier tips or displacement tips

Detection

· Applied Biosystems Genetic Analyzer (ABI 310, 3100, 3130, 3500, 3730)
· Performance optimized polymers: POP-4™ or POP-7™
· Hi-Di™ Formamide, Genetic Analysis Grade
· 1x Genetic Analyzer Buffer

· Micropipette/multipipette/dispenser with aerosol barrier tips or displacement

tips **Size Standard**
560 SIZER ORANGE (Devyser cat.# 8-A402) or GeneScan™ 600 LIZ® Size Standard (Life Technologies cat.# 4366589)

4.3 Dye Set Calibration

ABI 3100, 3130, 3730:
Use DEV-5 Dye Set MultiCap kit (Devyser cat# 8-A401) in the “Any5Dye” dye set.

ABI 3500:
Use DEV-5 Dye Set MultiCap kit (Devyser cat# 8-A401) and generate the DEV-5 dye set.

ABI 310 Matrix file generation:
Use: DEV-5 Dye Set SingleCap kit (Devyser cat# 8-A400). Run with module file “GS STR POP4 (1 mL) G5.md5”

5. STORAGE AND HANDLING REQUIREMENTS

A.

Store all components below -18 °C.

B.

The activated reaction mixes (prepared by addition of Resolution 21, 18, 13 and XY v2 RUO mixes to separate tubes of PCR Activator RUO) may be stored at +2 to +8 °C for at least 7 days or at below -18 °C for at least 90 days. Avoid repeated freeze-thawing.

C.

Dispose of unused reagents and waste in accordance with country, federal, state and local regulations.

D.

Do not mix reagents from different kit lot numbers.

6. SAMPLE REQUIREMENTS

Samples

The Devyser Resolution v2 RUO kits are intended for use with human genomic DNA extracted from whole blood, amniotic fluid and solid tissue samples.

Procedure and Storage

According to manufacturer's instructions for use.

Controls

It is recommended that suitable controls such as normal DNA and negative control (no DNA) are included in each run.

7. INSTRUCTIONS FOR USE

7.1 Workflow Devyser Resolution 21, 18, 13 and XY v2 RUO

The activated reaction mixes should be prepared before preparing the samples, if the complete pro-cess is performed in one day. Only if the samples are prepared the day before amplification or earlier, the opposite order is advisable.

The activated reaction mixes are prepared by adding each of the Resolution 21, 18, 13 and XY v2 RUO mixes to separate tubes of PCR Activator RUO.

Devyser Resolution v2 RUO should be used with a total PCR reaction volume of 25 µL. Changing the reaction volume will compromise the kit performance.

Ensure that the Resolution RUO mixes are completely thawed before use.

1. Centrifuge each tube briefly to collect the content. Do not vortex the tubes at this step.
2. Add 500 µL from each of the Resolution v2 mixes to separate tubes of PCR Activator.
3. Carefully mix by pipetting several times from the bottom of the tube.
4. Vortex the activated reaction mix tubes and centrifuge briefly to collect the content.
5. Add 20 µL of the activated reaction mixes to separate PCR reaction tubes.
6. Cap the reaction tubes and centrifuge briefly to collect the contents.
7. Continue to step 7.2

The activated reaction mixes are stable at +2-8 °C for at least 7 days or at below -18 °C for at least 90 days. Avoid repeated freeze-thawing.

7.2 Sample Preparation and PCR Amplification

DNA Extraction

According to manufacturer's instructions for use.

It is recommended that alternative DNA extraction methods and sample materials are thoroughly evaluated with the Devyser Resolution 21, 18, 13 and XY v2 RUO kits prior to the results being used for diagnostic use. For recommended PCR conditions and analysis settings (see below), results are consistently obtained at DNA concentrations between 2 and 30 ng/ PCR reaction (0,4-6 ng genomic DNA/µL sample).

Addition of Sample

Samples and controls should be added in a dedicated area separated from reagent preparation, amplification and detection areas.

1. Add 5 µL of sample (0,4 - 6 ng genomic DNA/µL sample) to each PCR reaction tube containing activated reaction mix (from step 7.1)
2. Cap the tubes and centrifuge briefly to collect the content.

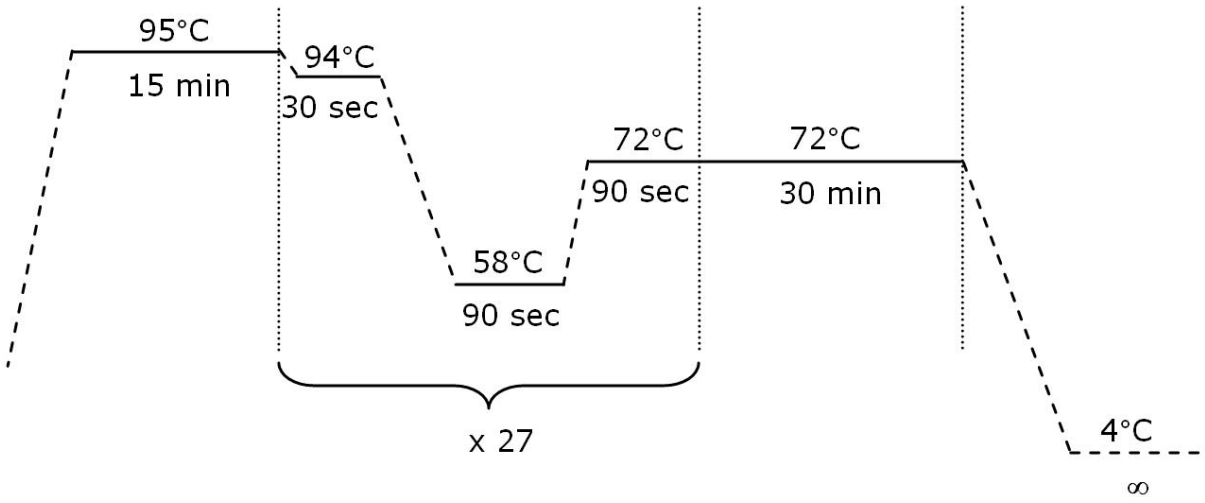
Amplification

Turn on the Thermal Cycler at least 30 minutes prior to amplification.
For Life Technologies/ABI GeneAmp® System 9700 set “ramp speed” to “9600 mode”.

For use of alternative thermal cyclers the following ramping rates must be applied: heating 0,8 ˚C/s, cooling 1,6 ˚C/s.

Amplification Area:
Program the Thermal Cycler for amplification according to the following thermal profile (consult the User´s Manual for additional information on programming and operation of the thermal cycler):

95 °C 15 min
94 °C 30 sec; 58 °C 1 min 30 sec; 72 °C 1 min 30 sec for 27 cycles
72 °C 30 min
4 °C FOREVER



1. Set reaction volume to 25 µL.
2. Start the amplification (duration approximately 3hrs).
3. Following amplification, remove the tubes containing completed PCR amplification reaction from the thermal cycler and place into a suitable holder. Centrifuge briefly to collect the content. Remove the caps carefully to avoid aerosol contamination. Do not bring amplified material into the pre-amplification areas. Amplified material should be restricted to amplification and detection areas.

7.3 Detection

Sample Preparation

Refer to the respective Life Technologies/ABI Genetic Analyzers User Manual for instructions on maintenance and handling. Prior to running the Devyser Resolution v2 RUO kits, the instrument must be spectrally calibrated to support detection of the dye set DEV-5. See section 4.3 for details.

Sample Preparation for Capillary Electrophoresis

1. Prepare a loading cocktail by combining and mixing 2 µL of the size standard (e.g. 560 SIZER ORANGE) with 100 µL Hi-Di™ Formamide (sufficient mix for 6 wells/tubes).
2. Vortex for 15 seconds.
3. Dispense 15 µL of the loading cocktail into the required number of wells of a microwell plate or into individual tubes (ABI310) to be placed on the Genetic Analyzer.
4. Add 1,5 µL of the sample PCR product to the corresponding well/tube containing loading cocktail.
5. Seal the plate/tubes.

Instrument Preparation

Create a sample sheet using the data collection software with the following settings:

- Sample ID
- Dye Set: Any5Dye/DEV-5
- Recommended run Module: See below for different polymers and instruments

Run Modules

The amount of PCR product injected into the capillaries can be adjusted by increasing/decreasing the injection time and/or injection voltage.

ABI 310 (Run with module file "GS STR POP4 (1 mL) G5.md5")

Run Parameters	POP-4
Capillary length	47 cm
Run temperature	60 ˚C
Injection voltage	15 kV
Injection time	5 - 15 s
Run voltage	15 kV
Run time	40 min

ABI 3100/3130

Run Parameters	POP-4/POP-7
Capillary length	36 cm
Run temperature	60 ˚C
Injection voltage	1,5 kV
Injection time	20 s
Run voltage	15 kV
Run time	1500 s

ABI 3500

Run Parameters	POP-7
Capillary length	50 cm
Run temperature	60 ˚C
Injection voltage	1,6 kV
Injection time	15 s
Run voltage	19,5 kV
Run time	1500 s

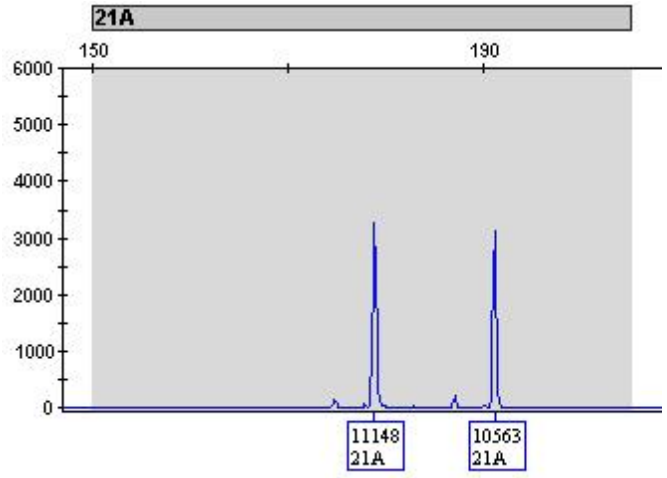
8. RESULTS AND ANALYSIS

Best practice guidelines for diagnosis of aneuploidy by QF-PCR have been established by the Clinical Molecular Genetics Society (UK and Association for Clinical Cytogenetics (UK and are available at: http://www.cmgs.org.uk

Principles of QF-PCR

Chromosome specific, repeated DNA sequences known as short tandem repeats (STRs are amplified by PCR. By using fluorescently labelled primers visualisation and quantification of the fluorescently labelled PCR products may be performed. Quantification can be achieved by calculating the ratio of the specific peak areas of the respective STR using an automated DNA sequencer. STRs vary in size between subjects, depending on the number of tetra repeats present on each allele. DNA amplified from normal subjects who are heterozygous (have alleles of different lengths for a specific STR marker is expected to show two peaks of different length with the same peak areas (figure 8.1. STR markers that are heterozygous are considered to be informative.

Figure 8.1. Heterozygous marker (area ratio 1:1



DNA amplified from subjects who are trisomic will exhibit either three peaks with similar area (figure 8.2), or only two peaks, one of them with twice as large area as the other (figure 8.3).

Figure 8.2. Trisomic marker (area ratio 1:1:1)

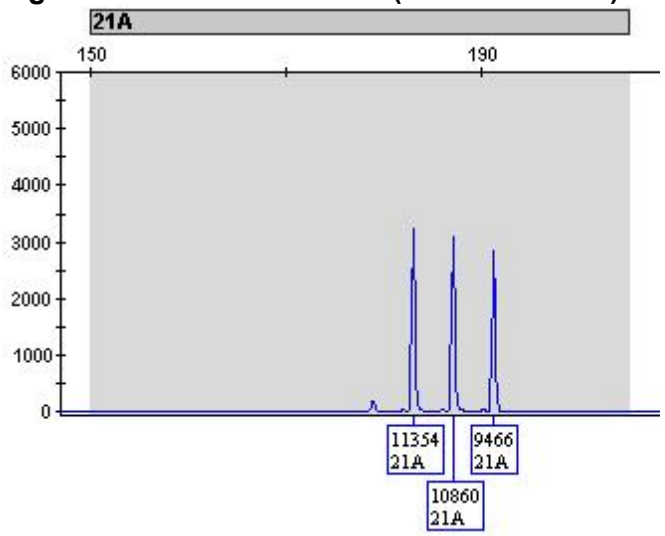
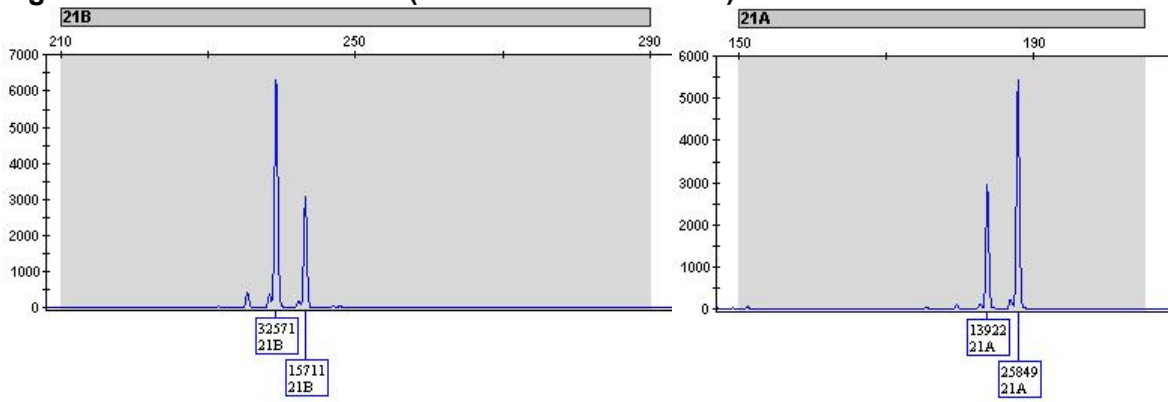
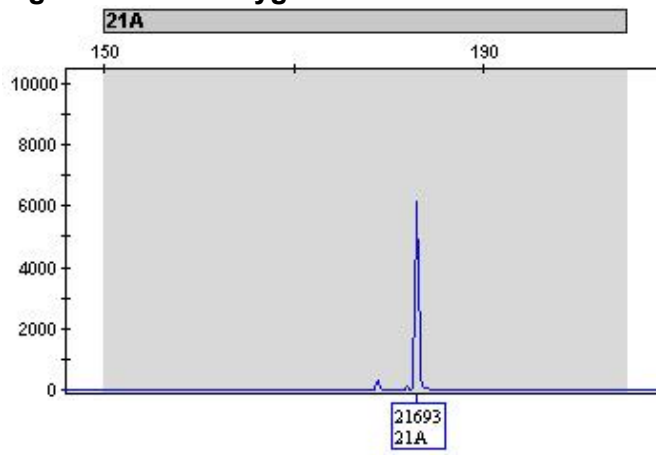


Figure 8.3. Trisomic markers (area ratios 2:1 and 1:2)



The presence of only one peak in a specific marker indicates homozygosity (have alleles of same length) and is considered to be uninformative. Subjects who are homozygous or monosomic for a specific STR marker will display only one peak (figure 8.4).

Figure 8.4. Homozygous/monosomic marker



X chromosome counting markers

The T1, T2 and T3 markers are non-polymorphic X chromosome counting markers that may be used to determine the number of X chromosomes when monosomy X is suspected. The X chromosome counting markers define sequences present on the X chromosome and an autosomal chromosome that are amplified using identical primers. The amplified marker fragments are separated according to length and the X chromosomal copy number is determined by fragment area ratio calculation.

In a normal female an X chromosome counting marker area ratio of 1:1 is expected (figure 8.5. In normal males and females with monosomy X a 2:1 ratio is expected for the T1 and T3 markers and a 1:2 ratio is expected for the T2 marker (figure 8.6.

Figure 8.5: Normal female T1, T2 and T3 markers (area ratio 1:1.

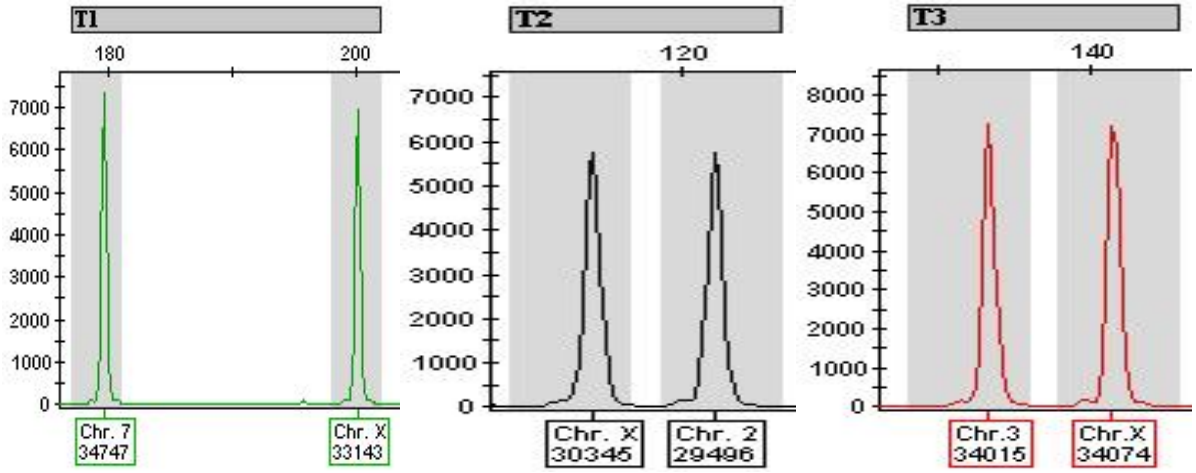
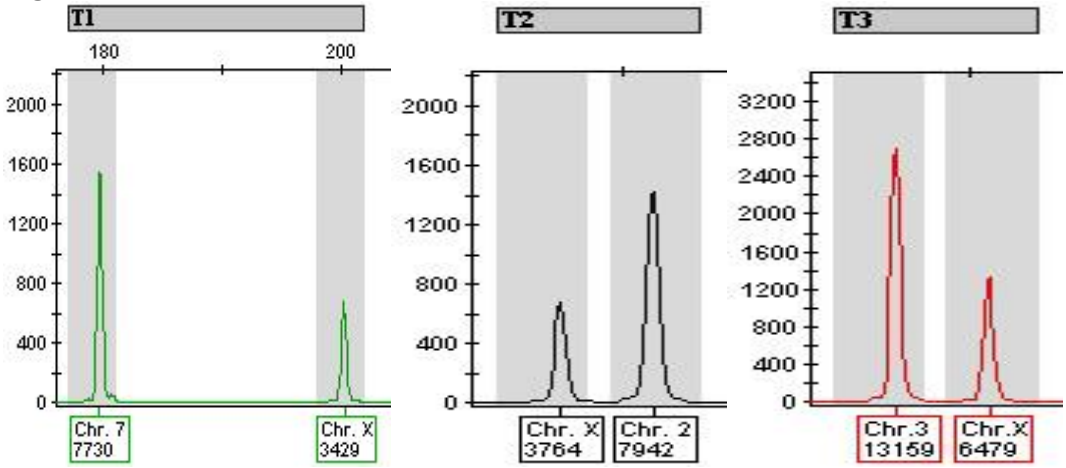


Figure 8.6: Normal male T1, T2 and T3 markers.



Non-Polymorphic Markers

The AMELXY and SRY markers amplify non-polymorphic sequences on the X (AMELX and Y (AMELY and SRY chromosomes and can be used to determine the presence or absence of a Y chromosome. AMELXY may be used to assess the relative number of X to Y chromosomes.

Pseudoautosomal XY Markers

The XY2 and XY3 markers are polymorphic STR markers present on both the X and Y chromosomes.

The ZFYX marker is a non-polymorphic (non-STR marker present on both the X and Y chromosomes.

These markers may be used to assess the total number of sex chromosomes when informative. It is not possible to determine which allele represents the X or Y chromosome.

Marker Overview Devyser Resolution 21 v2

ID	Location[1]	Marker	Marker size range (bp)[2]	Dye Colour
21A	21q21.3	D21S1435	150 - 208	Blue
21B	21q21.1	D21S11	215 - 290	Blue
21C	21q22.3	D21S1411	245 - 345	Yellow
21D	21q22.13	D21S1444	440 - 495	Yellow
21H	21q21.3	D21S1442	362 - 420	Red
21I	21q21.1	D21S1437	105 - 152	Yellow
21J	21q22.2	D21S2055	385 - 488	Blue
21K	21q21.2	D21S1409	160 - 220	Green
21M	21q22.11	D21S1280	290 - 390	Green

1. UCSC
2. Based on observed and calculated marker sizes using ABI3130, POP-7 polymer and 560 SIZER ORANGE. Please note that marker size ranges may vary depending on the instrument, polymer type and size marker used during electrophoresis.

Marker Overview Devyser Resolution 18 v2

ID	Location[1]	Marker	Marker size range (bp)[2]	Dye Colour
18A	18p11.31	D18S391	190 - 230	Blue
18B	18q12.3	D18S978	195 - 230	Yellow
18C	18q12.3	D18S535	300 - 350	Yellow
18D	18q22.1	D18S386	338 - 430	Green
18G	18q11.2	D18S1002	325 - 380	Blue
18I	18q21.31	D18S858	360 - 418	Yellow
18J	18p11.31	D18S976	440 - 495	Yellow
18M	18p11.32	GATA178F11	347 - 410	Red
18P	18q22.1	D18S1364	130 - 205	Green

1. UCSC
2. Based on observed and calculated marker sizes using ABI3130, POP-7 polymer and 560 SIZER ORANGE. Please note that marker size ranges may vary depending on the instrument, polymer type and size marker used during electrophoresis.

Marker Overview Devyser Resolution 13 v2

ID	Location[1]	Marker	Marker size range (bp)[2]	Dye Colour
13A	13q12.12	D13S742	224 - 334	Green
13B	13q21.32 - q21.33	D13S634	365 - 435	Blue
13C	13q31.3	D13S628	420 - 475	Yellow
13D	13q13.3	D13S305	435 - 505	Green
13E	13q22.1	D13S800	180 - 230	Yellow
13F	13q12.2	D13S252	255 - 320	Blue
13G	13q14.11	D13S325	312 - 417	Yellow
13I	13q.31.1	D13S317	155 - 212	Green
13K	13q21.1	D13S1492	100 - 175	Red

1. UCSC
2. Based on observed and calculated marker sizes using ABI3130, POP-7 polymer and 560 SIZER ORANGE. Please note that marker size ranges may vary depending on the instrument, polymer type and size marker used during electrophoresis.

Marker Overview Devyser Resolution XY v2

ID	Location[1]	Marker	Marker size range (bp)[2]	Dye Colour
AMELXY	Xp22.2 / Yp11.2	AMELX / AMELY	X = 104, Y = 110 (+/- 2bp)	Green
SRY	Yp11.31	SRY	235 (+/- 2bp)	Blue
ZFYX	Yp11.31 / Xp22.11	ZFY / ZFX	156 -167	Yellow
sY625	Yq11.21	sY625	254 (+/- 2bp)	Green
T1	7q34 / Xq13	-	7 = 180 / X = 200 (+/- 2 bp)	Green
T2	Xq23 / 2p23.3	-	X= 118 / 2 = 121 (+/- 2 bp)	Yellow
T3	3p24.2 / Xq21.1	-	3 = 137 X = 141 (+/- 2bp)	Red
X1	Xq26.2	DXS1187	120 - 172	Green
X2	Xq13.1	DXS981	262 - 300	Green
X3	Xq26.2-26.3	XHPRT	265 - 308	Yellow
X4	Xq21.33	DXS6809	292 - 342	Blue
X5	Xq25 - 26.1	DXS6854	392 - 430	Green
X8	Xq21.31	DXS6803	100 - 140	Blue
X9	Xq27.1-q27.2	DXS2390	312 - 357	Red
X10	Xp22.32	DXS6807	242 - 286	Blue
XY2	Xq21.31 / Yp11.31	DXYS267	175 - 217	Blue
XY3	Xp22.33 / Yp11.32	DXYS218	215 - 260	Red

1. UCSC
2. Based on observed and calculated marker sizes using ABI3130, POP-7 polymer and 560 SIZER ORANGE. Please note that marker size ranges may vary depending on the instrument, polymer type and size marker used during electrophoresis.

Performing Analysis

When performing manual analysis the marker peaks in an electrophoretogram should be identified according to the specific marker size ranges presented in the marker overview. Please note that marker size ranges may vary depending on the instrument, polymer type and size marker used during electrophoresis. The analysis of heterozygous markers displaying two allele peaks is performed by calculation of peak area ratios (peak1/peak2. Peak1 is the peak area of the shorter length fragment and peak2 is the peak area of the longer length fragment. See ratio criteria below for interpretation.

For markers displaying three allele peaks the ratio is always calculated starting with the area of the shortest length fragment (peak1, i.e. peak1/peak2 and peak1/peak3, respectively. Homozygous markers are considered uninformative.

Ratio Criteria (RC)

RC 1 is used when peak distance is <24bp
RC 2 is used when peak distance is ≥24bp

Allele ratios should not be calculated if the allele size difference is more than 40 bp since preferential amplification may cause skewed allele ratios.

Markers displaying two (2) allele peaks

Ratio	1:2	Inconclusive	1:1	Inconclusive	2:1
RC 1	<0,65	0,65-0,74	0,75-1,44	1,45-1,75	>1,75
RC 2	<0,65	0,65-0,74	0,75-1,54	1,55-1,75	>1,75

Markers displaying three (3) allele peaks

Ratio	Inconclusive	1:1:1	Inconclusive
RC 1	<0,74	0,75-1,44	>1,45
RC 2	<0,74	0,75-1,54	>1,55

Height Ratio

Height ratio may be calculated when an area ratio is classified as inconclusive. The same RC is applied as for area ratio calculation

Results Interpretation

To interpret a result as normal for a particular chromosome, at least two informative markers consistent with a normal genotype are required with all other markers being uninformative.
To interpret a result as abnormal for a particular chromosome, at least two informative markers consistent with an abnormal genotype are required with all other markers being uninformative.

Normal allelic pattern is determined by:
Marker showing two peaks of similar height/area and the peak ratio is classified as 1:1.

Abnormal allelic pattern is determined by:
a) Marker showing two peaks of differing height/area and the peak ratio is classified as 2:1/1:2.
b) Marker showing three peaks of similar height/area and the peak ratio is classified as 1:1:1

Monosomy X pattern is determined by:
a) All X and XY markers showing homozygous allelic pattern.
b) The AMELY and SRY peaks are not detected.
c) Marker T1 showing two peaks of differing height/area and the peak ratio is classified as 2:1.
d) Marker T2 showing two peaks of differing height/area and the peak ratio is classified as 1:2.
e) Marker T3 showing two peaks of differing height/area and the peak ratio is classified as 2:1.

Marker peaks with sizes outside given marker size ranges may appear.

Allele ratios should not be calculated if the allele size difference is more than 40 bp since preferential amplification may cause skewed allele ratios.

Troubleshooting

If a marker displays inconclusive results or is not detected a number of reasons are possible:
» Mosaicism
» Copy number variation (CNV)
» Microvariants due to specific repeat mutations
» Partial chromosome trisomy
» Stutter peak overlapping specific allele peaks
» Crosstalk between dye-channels

» Electrophoretic spike
» Preferential amplification causing skewing
» Contaminating DNA: second genotype, PCR amplicons
» Primer site polymorphism/alteration
» Somatic microsatellite mutation
» DNA concentration is too high or too low
» DNA is degraded or of poor quality
» Submicroscopic duplication/deletion of individual markers
» Allele size is more than 40 bp causing skewed allele ratios

In rare cases, amplification failure due to mutation of the primer site has been reported for the AMELY sequence.

In rare cases, ratio skewing due to mutation of the primer site has been reported for the T1 marker sequences.

If both normal and abnormal allelic patterns are obtained for a particular chromosome, it is recommended that follow-up studies are performed to identify the reason.

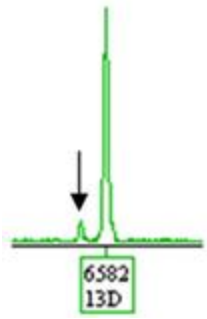
Copy number variants (CNVs have been reported for markers 13A, 13B, 13C, 13D, 18B, 18C, 18D, 21B, 21C, 21I, X3, XY3, AMELXY, ZFYX and T1.

If electrophoretograms are of poor quality the data should not be interpreted. The PCR product may be re-injected and re-analyzed.

PCR Artefacts

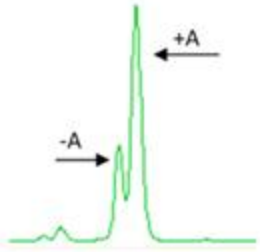
Stutter peaks (figure 8.7 are detected as extra peaks that are one repeat or a multiple of repeats smaller than the actual STR allele. Stutter peaks may be included in the ratio calculation. The stutter peak area is typically less than 15% of the corresponding STR peak area.

Figure 8.7. Stutter peak as indicated by the arrow.



-A peaks (figure 8.8) are detected as extra peaks that is one base pair shorter than the full length (+A peak) PCR product. -A peaks may be included in the ratio calculation.

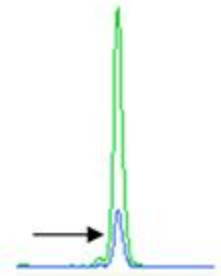
Figure 8.8. -A and +A peaks as indicated by the arrows.



Electrophoretic Artefacts

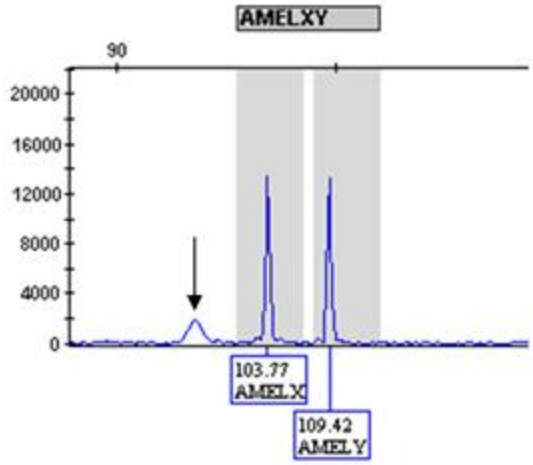
Crosstalk/bleed through between dye channels may occur during detection (Figure 8.9. Crosstalk appears as equally sized peaks in neighbouring dye channels and should be excluded from the analysis.

Figure 8.9. Crosstalk peak (from green to blue channel as indicated by the arrow.



Dye blobs may appear in the sample analysis range (figure 8.10). In general, dye blobs appear as broad, undefined peaks of a single colour and tend to occur relatively early in the data.

Figure 8.10. Dye blob as indicated by the arrow.



9. PERFORMANCE CHARACTERISTICS

This product is for research use only. Performance characteristics have not been established.

10. PROCEDURAL LIMITATIONS

Results from Devyser Resolution v2 RUO should not be used for diagnostic purposes. This product is intended for research use only

Use of this product should be limited to personnel trained in the techniques of PCR and capillary electrophoresis.

11. REFERENCES

PROFESSIONAL GUIDELINES FOR CLINICAL CYTOGENETICS AND CLINICAL MOLECULAR GENETICS. QF-PCR FOR THE DIAGNOSIS OF ANEUPLOIDY BEST PRACTICE GUIDELINES (2012, v3.01, January 2012.

12. NOTICE TO PURCHASER

Results from the Devyser Resolution v2 RUO kits should not be used for diagnostic purposes. This product is intended for research use only.

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Purchase of this product does not provide a license to perform PCR under patents owned by any third party.

13. CONTACT INFORMATION

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14. REVISION HISTORY

This document has been updated with the new logo and design on the first page. The content has not changed.

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New