Automated testing for HIV and Hepatitis B and C Virus

Reliable viral load monitoring of blood borne viruses

**AltoStar® HIV RT-PCR Kit 1.5**
- Detection and quantification of human immunodeficiency virus type 1 (HIV-1) specific RNA
- Validated for HIV-1 groups M, N and O
- Dual target detection: with amplification of separate regions of HIV-1 genome
- Targets detected: Target 1 = integrase (INT), Target 2 = protease (PRO)
- Quantification Standards calibrated against the 4th WHO International Standard for HIV-1 RNA (NIBSC code: 16/194; subtype B)

**AltoStar® HCV RT-PCR Kit 1.5**
- Detection and quantification of hepatitis C virus (HCV) specific RNA
- Validated for genotypes 1 to 6
- Quantification Standards calibrated against the 5th WHO International Standard for HCV NAT (NIBSC code: 14/150)

**AltoStar® HBV PCR Kit 1.5**
- Detection and quantification of hepatitis B virus (HBV) specific DNA
- Validated for genotypes A to H
- Quantification Standards calibrated against the 4th WHO International Standard for HBV DNA for Nucleic Acid Amplification Techniques (NIBSC code: 10/266)
AltoStar® portfolio

Viral load monitoring on high performance level

<table>
<thead>
<tr>
<th></th>
<th>AltoStar® HIV RT-PCR Kit 1.5</th>
<th>AltoStar® HBV PCR Kit 1.5</th>
<th>AltoStar® HCV RT-PCR Kit 1.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validated sample type</td>
<td>Human EDTA plasma</td>
<td>Human EDTA plasma</td>
<td>Human EDTA plasma and serum</td>
</tr>
<tr>
<td>Sample volume</td>
<td>1000 µl</td>
<td>1000 µl</td>
<td>1000 µl</td>
</tr>
<tr>
<td>Genotypes detected</td>
<td>HIV-1 Group M (subtypes A, C, D, E, F, G, H, AG), Group N, Group O Target 1: integrase (INT) Target 2: protease (PRO)</td>
<td>HBV genotypes A to H</td>
<td>HCV genotypes 1 to 6</td>
</tr>
<tr>
<td>Analytical specificity</td>
<td>≥ 99%</td>
<td>≥ 99%</td>
<td>≥ 99%</td>
</tr>
<tr>
<td>Limit of detection</td>
<td>30.0 IU/ml (95 % confidence interval: 21.3 - 54.3 IU/ml)</td>
<td>10.2 IU/ml (95 % confidence interval: 7.6 - 15.8 IU/ml).</td>
<td>11.1 IU/ml (95 % confidence interval: 7.8 - 18.5 IU/ml)</td>
</tr>
<tr>
<td>Linear range</td>
<td>100 - 10,000,000 IU/ml</td>
<td>20 - 10,000,000 IU/ml</td>
<td>25 - 10,000,000 IU/ml</td>
</tr>
</tbody>
</table>

For use with the automated AltoStar® Workflow

Efficiency, reliability and process safety

Assay principle
Real-time PCR-based test kits
Ready-to-use reagents

PCR time
2-2.5 hours

Purification
AltoStar® Purification Kit 1.5
One chemistry for DNA and RNA extraction

Throughput
Up to 48 analyses per run

IVD compliance
CE-IVD marked in vitro diagnostic test

<table>
<thead>
<tr>
<th>Product</th>
<th>Detection of</th>
<th>Rxns</th>
<th>GTIN</th>
<th>Order No.</th>
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</thead>
<tbody>
<tr>
<td>AltoStar® HIV RT-PCR Kit 1.5</td>
<td>Human immunodeficiency virus type 1 (quantitative) Genotypes M, N, O</td>
<td>96</td>
<td>4250453101243</td>
<td>AS0221513</td>
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<tr>
<td>AltoStar® HCV RT-PCR Kit 1.5</td>
<td>Hepatitis C virus (quantitative) Genotypes 1 to 6</td>
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<td>4250453100604</td>
<td>AS0211513</td>
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<tr>
<td>AltoStar® HBV PCR Kit 1.5</td>
<td>Hepatitis B virus (quantitative) Genotypes A to H</td>
<td>96</td>
<td>4250453100598</td>
<td>AS0201513</td>
</tr>
</tbody>
</table>

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