EU Declaration of Conformity according to Annex IV of the In Vitro Diagnostic Regulation 2017/746 (IVD), as per reviewed by the manufacturer

This is to certify that the IVD products listed in attachment are manufactured by D-tek s.a., Rue René Descartes, 19. BE-7000 Mons, Belgium (SRN : BE-MF-000024530) and under the certification of the Notified Body BSI Group The Netherlands B.V. (NB 2797, Certificate Number IVDR803698) following R EU 2017/746 Annex IX Conformity assessment based on a quality management system and on assessment of technical documentation.

- These products comply with all General Safety and Performance Requirements (Annex I) of the regulation 2017/746 on In Vitro Diagnostic Medical Devices.
  This compliance has been properly documented using a checklist created from Annex I and supported by technical documentation according to Annexes II and III.
- D-tek s.a. has a certified Quality System in place based on EN ISO13485 standard.
- This declaration is issued under the sole responsibility of the manufacturer.
- This Declaration of Conformity is signed below, certifying that the requirements of the regulation 2017/746 and the above applicable regulations and directives have been met and documented:
  - 1907/2006 (REACH) and related amendments

Done in Mons (Belgium), on January 1st, 2026.

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Product Family **BlueDot ANA IgG kits**
Basic UDI **542502368BDANAZF**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens relevant in Connective Tissue Diseases.

The kits are intended to confirm results of general anti-nuclear patterns obtained by immuno-fluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for IFA positive population and IFA negative with strong suspicion of autoimmune disorder.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits can only be used manually on a platform shaker or in an open automated immunodot processing system, programmed according to the pipetting scheme described in the IFUs of the kits.

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative when read on the BlueScan/DrDot Software reading system.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
ANA8D-24	**BlueDot ANA^{8} IgG**
ANA10D-24	**BlueDot ANA^{10} IgG**
ANA12D-24	**BlueDot ANA^{12} IgG**
ANA12SD-24	**BlueDot ANA^{12} Screen IgG**
ENAD-24	**BlueDot ENA^{6} IgG**
RLH12D-24	**BlueDot ANA + DFS-70 IgG**
CT10D-24	**BlueDot Connectivitis^{10} IgG**

Product Family **BlueDiver Dot ANA IgG kits**
Basic UDI **542502368BDDANAYE**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens relevant in Connective Tissue Diseases.

The kits are intended to confirm results of general anti-nuclear patterns obtained by immuno-fluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for IFA positive population and IFA negative with strong suspicion of autoimmune disorder.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits are strictly foreseen as automated tests and can only be used in a BlueDiver Instrument Model I or II (BDI I or BDI II respectively).

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative.

For a semi-quantification of the test results, it is necessary to use the BlueScan/DrDot Software reading system. This system is not included in the BDI I but is included in the BDI II.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
ANA8DIV-24	**BlueDiver Dot ANA^{8} IgG**
ANA10DIV-24	**BlueDiver Dot ANA^{10} IgG**
ANA12DIV-24	**BlueDiver Dot ANA^{12} IgG**
ANA12SDIV-24	**BlueDiver Dot ANA^{12} Screen IgG**
ENADIV-24	**BlueDiver Dot ENA^{6} IgG**
PRL12DIV-24	**BlueDiver Dot PRL^{12} IgG**
RLH12DIV-24	**BlueDiver Dot ANA + DFS-70 IgG**
CT10DIV-24	**BlueDiver Dot Connectivitis^{10} IgG**

Product Family **BlueDiver Quantrix ANA IgG kits**
Basic UDI **542502368BDQANA3C**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens relevant in Connective Tissue Diseases.

The kits are intended to confirm results of general anti-nuclear patterns obtained by immuno-fluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for IFA positive population and IFA negative with strong suspicion of autoimmune disorder.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits are strictly foreseen as automated tests and can only be used in a BlueDiver Instrument Model I or II (BDI I or BDI II respectively).

Detection of the different IgG autoantibodies is semi-quantitative.

For this semi-quantification of the test results, it is necessary to use the BlueScan/DrDot Software reading system. This system is not included in the BDI I but is included in the BDI II.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
ANA19Q-24	**BlueDiver Quantrix ANA^{19} IgG**
ANA25Q-24	**BlueDiver Quantrix ANA^{25} IgG**

Product Family **BlueDot Chromatin IgG kits**
Basic UDI **542502368BDCHROMATINFW**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens relevant in Connective Tissue Diseases.

The kits are intended to confirm results of homogeneous patterns obtained by immuno-fluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for IFA positive population and IFA negative with strong suspicion of autoimmune disorder.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits can only be used manually on a platform shaker or in an open automated immunodot processing system, programmed according to the pipetting scheme described in the IFUs of the kits.

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative when read on the BlueScan/DrDot Software reading system.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
CHRD-24	**BlueDot Chromatin IgG**
CHR4D-24	**BlueDot Chromatin^4 IgG**

Product Family **BlueDiver Dot Chromatin IgG kits**
Basic UDI **542502368BDDCHROMATIN6Y**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens relevant in Connective Tissue Diseases.

The kits are intended to confirm results of homogeneous patterns obtained by immuno-fluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for IFA positive population and IFA negative with strong suspicion of autoimmune disorder.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits are strictly foreseen as automated tests and can only be used in a BlueDiver Instrument Model I or II (BDI I or BDI II respectively).

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative.

For a semi-quantification of the test results, it is necessary to use the BlueScan/DrDot Software reading system. This system is not included in the BDI I but is included in the BDI II.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
CHRDIV-24	**BlueDiver Dot Chromatin IgG**
CHR4DIV-24	**BlueDiver Dot Chromatin^4 IgG**

Product Family **BlueDot Granular IgG kits**
Basic UDI **542502368BDGRANULARQV**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens relevant in Connective Tissue Diseases.

The kits are intended to confirm results of speckled/granular patterns obtained by immuno-fluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for IFA positive population and IFA negative with strong suspicion of autoimmune disorder.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits can only be used manually on a platform shaker or in an open automated immunodot processing system, programmed according to the pipetting scheme described in the IFUs of the kits.

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative when read on the BlueScan/DrDot Software reading system.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
GR12D-24	**BlueDot Granular^{12} IgG**

Product Family **BlueDiver Dot Granular IgG kits**
Basic UDI **542502368BDDGRANULARDB**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens relevant in Connective Tissue Diseases.

The kits are intended to confirm results of speckled/granular patterns obtained by immuno-fluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for IFA positive population and IFA negative with strong suspicion of autoimmune disorder.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits are strictly foreseen as automated tests and can only be used in a BlueDiver Instrument Model I or II (BDI I or BDI II respectively).

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative.

For a semi-quantification of the test results, it is necessary to use the BlueScan/DrDot Software reading system. This system is not included in the BDI I but is included in the BDI II.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
GR12DIV-24	**BlueDiver Dot Granular^{12} IgG**

Product Family **BlueDot Cytoplasm IgG kits**
Basic UDI **542502368BDCYTOPLASMUE**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens relevant in Connective Tissue Diseases.

The kits are intended to confirm results of cytoplasmic patterns obtained by immuno-fluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for IFA positive population and IFA negative with strong suspicion of autoimmune disorder.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits can only be used manually on a platform shaker or in an open automated immunodot processing system, programmed according to the pipetting scheme described in the IFUs of the kits.

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative when read on the BlueScan/DrDot Software reading system.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
CY6D-24	**BlueDot Cytoplasm^{6} IgG**

Product Family **BlueDiver Dot Cytoplasm IgG kits**
Basic UDI **542502368BDDCYTOPLASMKG**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens relevant in Connective Tissue Diseases.

The kits are intended to confirm results of cytoplasmic patterns obtained by immuno-fluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for IFA positive population and IFA negative with strong suspicion of autoimmune disorder.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits are strictly foreseen as automated tests and can only be used in a BlueDiver Instrument Model I or II (BDI I or BDI II respectively).

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative.

For a semi-quantification of the test results, it is necessary to use the BlueScan/DrDot Software reading system. This system is not included in the BDI I but is included in the BDI II.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
CY6DIV-24	**BlueDiver Dot Cytoplasm^{6} IgG**

Product Family **BlueDot OVERLAP kits**
Basic UDI **542502368BDPMSCLCN**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits allowing the detection, in human serum, of specific IgG autoantibodies in the context of an overlap syndrome Polymyositis/Autoimmune Scleroderma diagnostic.

The kits are intended to be used as confirmatory tests following indirect immunofluorescence assay (IFA), screening and reference method for auto-antibodies detection.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits can only be used manually on a platform shaker or in an open automated immunodot processing system, programmed according to the pipetting scheme described in the IFUs of the kits.

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative when read on the BlueScan/DrDot Software reading system.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
PMS8D-24	**BlueDot Polymyositis/Scleroderma^{8} IgG**
PMS12D-24	**BlueDot Polymyositis/Scleroderma^{12} IgG**

Product Family **BlueDiver Dot OVERLAP kits**
Basic UDI **542502368BDDPMSCLLT**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits allowing the detection, in human serum, of specific IgG autoantibodies in the context of an overlap syndrome Polymyositis/Autoimmune Scleroderma diagnostic.

The kits are intended to be used as confirmatory tests following indirect immunofluorescence assay (IFA), screening and reference method for auto-antibodies detection.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits are strictly foreseen as automated tests and can only be used in a BlueDiver Instrument Model I or II (BDI I or BDI II respectively).

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative.

For a semi-quantification of the test results, it is necessary to use the BlueScan/DrDot Software reading system. This system is not included in the BDI I but is included in the BDI II).

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
PMS8DIV-24	**BlueDiver Dot Polymyositis/Scleroderma^{8} IgG**
PMS12DIV-24	**BlueDiver Dot Polymyositis/Scleroderma^{12} IgG**

Product Family **BlueDot SCLERODERMA kits**
Basic UDI **542502368BDSCLERODERMAK9**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits allowing the detection, in human serum, of specific IgG autoantibodies in the context of an Autoimmune Scleroderma diagnostic.

The kits are confirmatory tests following indirect immunofluorescence assay (IFA), screening and reference method for auto-antibodies detection.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits can only be used manually on a platform shaker or in an open automated immunodot processing system, programmed according to the pipetting scheme described in the IFUs of the kits.

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative when read on the BlueScan/DrDot Software reading system.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
SCL10D-24	**BlueDot Scleroderma^{10} IgG**
SCL12D-24	**BlueDot Scleroderma^{12} IgG**

Product Family **BlueDiver Dot SCLERODERMA kits**
Basic UDI **542502368BDDSCLERODERMAKH**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits allowing the detection, in human serum, of specific IgG autoantibodies in the context of an Autoimmune Scleroderma diagnostic.

The kits are are intended to be used as confirmatory tests following indirect immunofluorescence assay (IFA), screening and reference method for auto-antibodies detection.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits are strictly foreseen as automated tests and can only be used in a BlueDiver Instrument Model I or II (BDI I or BDI II respectively).

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative.

For a semi-quantification of the test results, it is necessary to use the BlueScan/DrDot Software reading system. This system is not included in the BDI I but is included in the BDI II).

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
SCL10DIV-24	**BlueDiver Dot Scleroderma^{10} IgG**
SCL12DIV-24	**BlueDiver Dot Scleroderma^{12} IgG**

Product Family **BlueDot APS**
Basic UDI **542502368BDAPS2U**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens relevant in the Antiphospholipid Syndrome.

The kits are intended to confirm results of patterns obtained by Enzyme Immunoassay techniques; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits can only be used manually on a platform shaker or in an open automated immunodot processing system, programmed according to the pipetting scheme described in the IFUs of the kits.

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative when read on the BlueScan/DrDot Software reading system.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
APSGD-24	**BlueDot APS IgG**

Product Family **BlueDiver Dot APS**
Basic UDI **542502368BDDAPSZQ**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens relevant in the Antiphospholipid Syndrome.

The kits are intended to confirm results of patterns obtained by Enzyme Immunoassay techniques; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits are strictly foreseen as automated tests and can only be used in a BlueDiver Instrument Model I or II (BDI I or BDI II respectively).

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative.

For a semi-quantification of the test results, it is necessary to use the BlueScan/DrDot Software reading system. This system is not included in the BDI I but is included in the BDI II.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
APSGDIV-24	**BlueDiver Dot APS IgG**

Product Family **BlueDot MYOSITIS kits**
Basic UDI **542502368BDMYOSITIS74**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits allowing the detection, in human serum, of specific IgG autoantibodies in the context of an auto-immune myositis diagnostic.

The kits are intended to confirm results of patterns obtained by immunofluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits can only be used manually on a platform shaker or in an open automated immunodot processing system, programmed according to the pipetting scheme described in the IFUs of the kits.

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative when read on the BlueScan/DrDot Software reading system.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
MYO7D-24	**BlueDot Myositis[7] IgG**
MYO12D-24	**BlueDot Myositis[12] IgG**
MYOS12D-24	**BlueDot Myositis[12] SAE IgG**
SYN10D-24	**BlueDot Synthetase[10] IgG**

Product Family **BlueDiver Dot MYOSITIS kits**
Basic UDI **542502368BDDMYOSITISTF**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits allowing the detection, in human serum, of specific IgG autoantibodies in the context of an auto-immune myositis diagnostic.

The kits are intended to confirm results of patterns obtained by immunofluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits are strictly foreseen as automated tests and can only be used in a BlueDiver Instrument Model I or II (BDI I or BDI II respectively).

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative.

For a semi-quantification of the test results, it is necessary to use the BlueScan/DrDot Software reading system. This system is not included in the BDI I but is included in the BDI II).

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
MYOS12DIV-24	**BlueDiver Dot Myositis[12] SAE IgG**
SYN10DIV-24	**BlueDiver Dot Synthetase[10] IgG**

Product Family **BlueDot GAD kits**
Basic UDI **542502368BDGADZC**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens relevant in the Stiff Person Syndrome.

They are intended to confirm results obtained by other screening methods (ELISA, RIA, …) as an aid in the diagnostic of a stiff man syndrome.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits can only be used manually on a platform shaker or in an open automated immunodot processing system, programmed according to the pipetting scheme described in the IFUs of the kits.

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative when read on the BlueScan/DrDot Software reading system.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
GAD-24	**BlueDot GAD IgG**

Product Family **BlueDiver Dot GAD kits**
Basic UDI **542502368BDDGADYB**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens relevant in the Stiff Person Syndrome.

They are intended to confirm results obtained by other screening methods (ELISA, RIA, …) as an aid in the diagnostic of a stiff man syndrome.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits are strictly foreseen as automated tests and can only be used in a BlueDiver Instrument Model I or II (BDI I or BDI II respectively).

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative.

For a semi-quantification of the test results, it is necessary to use the BlueScan/DrDot Software reading system. This system is not included in the BDI I but is included in the BDI II).

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
GADIV-24	**BlueDiver Dot GAD IgG**

Product Family **BlueDot ANCA**
Basic UDI **542502368BDANCAYR**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens relevant in Vasculitis and Goodpasture Syndrome.
The kits are intended to confirm results of patterns obtained by immunofluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.
The tests are intended for a large, routine population.
These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.
The kits can only be used manually on a platform shaker or in an open automated immunodot processing system, programmed according to the pipetting scheme described in the IFUs of the kits.
Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative when read on the BlueScan/DrDot Software reading system.
More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
ANCAGD-24	**BlueDot ANCA^{+GBM} IgG**

Product Family **BlueDiver Dot ANCA**
Basic UDI **542502368BDDANCA4F**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens antigens relevant in Vasculitis and Goodpasture Syndrome.
The kits are intended to confirm results of patterns obtained by immunofluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.
The tests are intended for a large, routine population.
These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.
The kits are strictly foreseen as automated tests and can only be used in a BlueDiver Instrument Model I or II (BDI I or BDI II respectively).
Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative.
For a semi-quantification of the test results, it is necessary to use the BlueScan/DrDot Software reading system. This system is not included in the BDI I but is included in the BDI II.
More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
ANCAGDIV-24	**BlueDiver Dot ANCA^{+GBM} IgG**

Product Family **BlueDot LIVER kits**
Basic UDI **542502368BDLIVERBF**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG or IgG/IgM autoantibodies in the context of an auto-immune hepatitis or Primary Biliary Cirrhosis diagnostic.

The kits are intended to confirm results of patterns obtained by immunofluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits can only be used manually on a platform shaker or in an open automated immunodot processing system, programmed according to the pipetting scheme described in the IFUs of the kits.

Detection of the different IgG or IgG/IgM autoantibodies can be either qualitative or semi-quantitative when read on the BlueScan/DrDot reading system.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
LISD-24	**BlueDot Liver^{5} IgG**
LI7D-24	**BlueDot Liver^{7} IgG**
LI10D-24	**BlueDot Liver^{10} IgG**
MI2D-24	**BlueDot Mitochondria^{2} IgG + IgM**

Product Family **BlueDiver Dot LIVER kits**
Basic UDI **542502368BDDLIVERKL**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG or IgG/IgM autoantibodies in the context of an auto-immune hepatitis or Primary Biliary Cirrhosis diagnostic.

The kits are intended to confirm results of patterns obtained by immunofluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits are strictly foreseen as automated tests and can only be used in a BlueDiver Instrument Model I or II (BDI I or BDI II respectively).

Detection of the different IgG or IgG/IgM autoantibodies can be either qualitative or semi-quantitative.

For a semi-quantification of the test results, it is necessary to use the BlueScan/DrDot Software reading system. This system is not included in the BDI I but is included in the BDI II).

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
LISDIV-24	**BlueDiver Dot Liver^{5} IgG**
LI7DIV-24	**BlueDiver Dot Liver^{7} IgG**
LI10DIV-24	**BlueDiver Dot Liver^{10} IgG**
MI2DIV-24	**BlueDiver Dot Mitochondria^{2} IgG + IgM**

Product Family **BlueDiver Quantrix LIVER kits**
Basic UDI **542502368BDQLIVERQV**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies in the context of an auto-immune hepatitis or Primary Biliary Cirrhosis diagnostic.

The kits are intended to confirm results of patterns obtained by immunofluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits are strictly foreseen as automated tests and can only be used in a BlueDiver Instrument Model I or II (BDI I or BDI II respectively).

Detection of the different IgG autoantibodies is semi-quantitative.

For this semi-quantification of the test results, it is necessary to use the BlueScan/DrDot Software reading system. This system is not included in the BDI I but is included in the BDI II).

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
LI10Q-24	**BlueDiver Quantrix Liver[10] IgG**

Product Family **BlueDot Celiac kits**
Basic UDI **542502368BDCELIACE4**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgA or IgG autoantibodies relevant in the Celiac Disease.

The kits are intended to confirm results of patterns obtained by immunofluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits can only be used manually on a platform shaker or in an open automated immunodot processing system, programmed according to the pipetting scheme described in the IFUs of the kits.

Detection of the different IgA or IgG autoantibodies can be either qualitative or semi-quantitative when read on the BlueScan/DrDot Software reading system.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
ENDA-24	**BlueDot Celiac IgA**
ENDG-24	**BlueDot Celiac IgG**

Product Family **BlueDiver Dot Celiac kits**
Basic UDI **542502368BDDCELIACR5**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgA or IgG autoantibodies against antigens relevant in the Celiac Disease.

The kits are intended to confirm results of patterns obtained by immunofluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits are strictly foreseen as automated tests and can only be used in a BlueDiver Instrument Model I or II (BDI I or BDI II respectively).

Detection of the different IgA or IgG autoantibodies can be either qualitative or semi-quantitative.

For a semi-quantification of the test results, it is necessary to use the BlueScan/DrDot Software reading system. This system is not included in the BDI I but is included in the BDI II.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
ENDADIV-24	**BlueDiver Dot Celiac IgA**
ENDGDIV-24	**BlueDiver Dot Celiac IgG**

Product Family **BlueDot CROHN kits**
Basic UDI **542502368BDCROHN99**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgA/IgG autoantibodies against antigens relevant in Crohn's Disease.

The kits are intended to confirm results of patterns obtained by immunofluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits can only be used manually on a platform shaker or in an open automated immunodot processing system, programmed according to the pipetting scheme described in the IFUs of the kits.

Detection of the different IgA/IgG autoantibodies can be either qualitative or semi-quantitative when read on the BlueScan/DrDot Software reading system.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
ASCCD-24	**BlueDot ASCA IgG + IgA**

Product Family **BlueDiver Dot CROHN kits**
Basic UDI **542502368BDDCROHNHE**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgA/IgG autoantibodies against antigens relevant in Crohn's Disease.

The kits are intended to confirm results of patterns obtained by immunofluorescence, the screening and reference method in autoimmunity; the kits are intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits are strictly foreseen as automated tests and can only be used in a BlueDiver Instrument Model I or II (BDI I or BDI II respectively).

Detection of the different IgA/IgG autoantibodies can be either qualitative or semi-quantitative.

For a semi-quantification of the test results, it is necessary to use the BlueScan/DrDot Software reading system. This system is not included in the BDI I but is included in the BDI II).

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
ASCCDIV-24	**BlueDiver Dot ASCA IgG+IgA**

Product Family **BlueDot Gastritis kits**
Basic UDI **542502368BDGASTRITISLY**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens relevant in Autoimmune Gastritis.

They are intended to confirm results of patterns obtained by immunofluorescence, the screening and reference method in autoimmunity and obtained by Enzyme Immunoassay techniques; the kit is intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits can only be used manually on a platform shaker or in an open automated immunodot processing system, programmed according to the pipetting scheme described in the IFUs of the kits.

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative when read on the BlueScan/DrDot Software reading system.

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
IFPCAD-24	**BlueDot Gastritis IgG**

Product Family **BlueDiver Dot Gastritis kits**
Basic UDI **542502368BDDGASTRITISC2**
Risk Class **B**

Intended Use

The kits under this Basic UDI are immunodot kits intended for the detection, in human sera only, of IgG autoantibodies against antigens relevant in Autoimmune Gastritis.

They are intended to confirm results of patterns obtained by immunofluorescence, the screening and reference method in autoimmunity and obtained by Enzyme Immunoassay techniques; the kit is intended as an aid in the diagnosis of several autoimmune diseases.

The tests are intended for a large, routine population.

These kits are strictly reserved for professional use in clinical analysis laboratories. Prior training is strongly recommended.

The kits are strictly foreseen as automated tests and can only be used in a BlueDiver Instrument Model I or II (BDI I or BDI II respectively).

Detection of the different IgG autoantibodies can be either qualitative or semi-quantitative.

For a semi-quantification of the test results, it is necessary to use the BlueScan/DrDot Software reading system. This system is not included in the BDI I but is included in the BDI II).

More information dedicated to each kit of this family is available in the Instructions for Use of each kit.

D-tek Kits under this Basic UDI

D-tek Kit Reference	Kit Name
IFPCADIV-24	**BlueDiver Dot Gastritis IgG**