List of materials included under RFP-DAN-2017-

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Schedule 1: RDT Antibody (Ab) detection technology

ITEM 010
U481900 ZIKV RDT Ab detection test

GENERAL DESCRIPTION
Single use disposable ZIKV rapid serology to detect ZIKV specific antibodies (IgM and/or IgG)

INTENDED USE
Screening/ surveillance of pregnant women for acute ZIKV infection at point-of-care

GENERAL SPECIFICATIONS
Product technology status: Design freeze stage/lockdown
Format: Single use disposable rapid test
Principle of assay: Rapid serology assay to detect ZIKV specific antibodies (IgM and/or IgG)
Type of result: Qualitative
Intended testing population: Pregnant women and sexual partners
Intended user of the test: Health care worker at point-of-care
Intended setting of use: point-of-care (Primary Health Care Level). Suitable for outreach/ resource limited settings
Output: Detection of ZIKV specific Ab (IgM and/or IgG)

ASSAY PERFORMANCE
Sensitivity: minimum > 85% for specific ZIKV Ab (detecting IgM in early stages of infection and for IgG, both early and late stages of an infection)
Specificity: minimum > 85% for specific ZIKV Ab
Analytical specificity- cross reactivity: Evaluated and show no significant cross reactivity against Dengue (serotypes 1-4 both from primary and secondary infections), Yellow Fever vaccination, Chikungunya, West Nile virus
Analytical specificity-Interference substances: Evaluated over the expected clinical range of the potential interfering substance
Immunoglobulin class specificity: no cross reactivity of IgG in IgM assay (and no cross reactivity of IgM in IgG assays)
Clinical Evidence (diagnostic sensitivity and specificity): provide details of the clinical evaluation study including:
* 50 confirmed positive ZIKV clinical specimens
* 50 specified from pregnant women from affected area
* 50-100 specimen with confirmed negative ZIKV / negative other arbovirus infections
* 25-50 specimen from individuals in target area for use of the assay
* using specimens sourced globally"
Technical file: include in addition to the herein mentioned technical specifications: product design, its workflow, Analytical and clinical studies for validation and verification of the test, field testing studies (accuracy and correlation with applicable standards, and its clinical effectiveness, robustness of the technology in low-income country environments), repeatability and reproducibility of results (addressing if any lot variations), any assay limitations....

ASSAY IN PRACTICE
Specimen type used for analysis: Capillary finger-prick- blood/ whole blood
Specimen volume used for analysis: Approx. 20ul
Time to get a result: Approx. 20 min (from specimen collection to test result)
Interpretation of the results: Visually
Rapid test kit components: Rapid test kit contains all necessary reagents to complete ZIKV specific Ab (IgM and or IgG) from specimen collection to test-result
Internal quality control: Built-in quality positive and negative control lines
Temperature during transport: Approx. 10 - 35°C
Operating temperature and storage: Approx. 10 - 35°C
Operating relative humidity: Approx. 10 - 90% non-condensing
Shelf life for unopened test and buffer solution: Minimum 6 months, 12 months preferably
Shelf for opened tests and buffer solution:
   Test strip/cartridge: use immediately after opening pouch containing single-use test.
   Buffer solution: minimum 6 months

EASE OF USE
Product operational procedure: Around 3-5 steps from specimen collection to producing a test result, preferably
Languages of the Instructions for use (IFU): English, French and Spanish/Portuguese, more preferably
Level of education (cadre) to perform the test: All levels of health care workers
Health care system that fit the technology: From primary health care level upwards

ITEMS SUPPLIED WITH
Kit contains: The Packaging box, re-closable for safe storage and transportation is supplied minimum with the following items:
   · Single use disposable rapid tests;
   · Blood transfer devices;
   · Disinfection swabs;
   · Safety lancets;
   · Buffer solution;
   · Instructions for use in English, French and Spanish/Portuguese.
Other items supplied with: Indicate other items the product is supplied with, apart from the ones mentioned above
Sizes of the test kit box: Indicate all the pack sizes available for this product

ACCESSORIES
Accessories, and other products that are intended to be used in combination with the IVD but are not provided: none

TRAINING/PRODUCT PHOTO
Type of training(s) offered to customers: no or minimal user training
Training material available to customers: Training poster, pictogram-based step-by-step testing procedures, training videos, preferably
Languages of the training(s): English, French and Spanish/Portuguese, more preferably
Training material: Available in electronic format
Packaging photos: photo for kit components, primary and secondary packaging
REGULATORY / OTHER

Quality Management System (QMS): product and manufacturer must comply to ISO13485 or an equivalent QMS recognized by a regulatory authority of the founding members of the GHTF

Market approval certificate: product and manufacturer conform to European directive CE 98/79 IVD (or equivalent) (if available)

WHO Prequalification: PQ approval if available

Emergency listing: WHO EUAL and / or FDA EUA, if available

Hazardous classification: including Material Safety Data Sheets (MSDS).
ITEM 020

U481900  Multiplex (ZIKV / X Arbovirus) RDT Ab detection test

GENERAL DESCRIPTION
Single use disposable ZIKV rapid serology to simultaneously detect ZIKV / X Arbovirus (Dengue virus DENV and/or Chikungunya virus CHKNV and/or Yellow fever virus YF and/or West Nile Virus WNV) specific antibodies (IgM and/or IgG)

INTENDED USE
Screening/ surveillance of pregnant women for acute ZIKV infection at point-of-care

GENERAL SPECIFICATIONS
Product technology status: Design freeze stage/lockdown
Format: Single use disposable rapid test
Principle of assay: Rapid multiplex serology assay simultaneously detect ZIKV / X Arbovirus (Dengue virus DENV and/or Chikungunya virus CHKNV and/or Yellow fever virus YF and/or West Nile Virus WNV) specific antibodies (IgM and/or IgG)
Type of result: Qualitative
Intended testing population: Pregnant women and sexual partners
Intended user of the test: Health care worker at point-of-care
Intended setting of use: point-of-care (Primary Health Care Level). Suitable for outreach/ resource limited settings
Output: Simultaneous detection of ZIKV specific Ab (IgM and/or IgG) and/or DENV (1-4 serotypes IgM and/or IgG and/or CHKNV (IgM and/or IgG) and/or YF (IgM and/or IgG) and/or WNV (IgM and/or IgG)

ASSAY PERFORMANCE
Sensitivity: minimum > 85% for specific ZIKV Ab + X arbovirus (DENV/ CHKNV/YF/WNV) (detecting IgM in early stages of infection and for IgG, both early and late stages of an infection)
Specificity: minimum > 85% for specific ZIKV Ab + X arbovirus (DENV/ CHKNV/YF/WNV)
Analytical specificity- cross reactivity: Evaluated and show no significant cross reactivity against Dengue (serotypes 1-4 both from primary and secondary infections), Yellow Fever vaccination, Chikungunya, West Nile virus
Analytical specificity-Interference substances: Evaluated over the expected clinical range of the potential interfering substance
Immunoglobulin class specificity: no cross reactivity of IgG in IgM assay (and no cross reactivity of IgM in IgG assays)
Clinical Evidence (diagnostic sensitivity and specificity): provide details of the clinical evaluation study including:
* 50 confirmed positive ZIKV clinical specimens
* 50 specified from pregnant women from affected area
* 50-100 specimen with confirmed negative ZIKV / negative other arbovirus infections
* 25-50 specimen from individuals in target area for use of the assay
* using specimens sourced globally"
Technical file: include in addition to the herein mentioned technical specifications: product design, its workflow, Analytical and clinical studies for validation and verification of the test, field testing
studies (accuracy and correlation with applicable standards, and its clinical effectiveness, robustness of the technology in low-income country environments), repeatability and reproducibility of results (addressing if any lot variations), any assay limitations....

ASSAY IN PRACTICE
Specimen type used for analysis: Capillary finger-prick- blood/ whole blood
Specimen volume used for analysis: Approx. 20ul
Time to get a result: Approx. 20 min (from specimen collection to test result)
Interpretation of the results: Visually
Rapid test kit components: Rapid test kit contains all necessary reagents to complete multiplex ZIKV / X Arbovirus specific Ab (IgM and or IgG) from specimen collection to test-result
Internal quality control: Built-in quality positive and negative control lines
Temperature during transport: Approx. 10 - 35°C
Operating temperature and storage: Approx. 10 - 35°C
Operating relative humidity: Approx. 10 - 90% non-condensing
Shelf life for unopened test and buffer solution: Minimum 6 months, 12 months preferably
Shelf for opened tests and buffer solution:
  Test strip/ cartridge: use immediately after opening pouch containing single-use test.
  Buffer solution: minimum 6 months

EASE OF USE
Product operational procedure: Around 3-5 steps from specimen collection to producing a test result, preferably
Languages of the Instructions for use (IFU): English, French and Spanish/Portuguese, more preferably
Level of education (cadre) to perform the test: All levels of health care workers
Health care system that fit the technology: From primary health care level upwards

ITEMS SUPPLIED WITH
Kit contains: The Packaging box, re-closable for safe storage and transportation is supplied minimum with the following items:
  · Single use disposable rapid tests;
  · Blood transfer devices;
  · Disinfection swabs;
  · Safety lancets;
  · Buffer solution;
  · Instructions for use in English, French and Spanish/Portuguese."
Other items supplied with: Indicate other items the product is supplied with, apart from the ones mentioned above
Sizes of the test kit box: Indicate all the pack sizes available for this product

ACCESSORIES
Accessories, and other products that are intended to be used in combination with the IVD but are not provided: none

TRAINING/PRODUCT PHOTO
Type of training(s) offered to customers: no or minimal user training
Training material available to customers: Training poster, pictogram-based step-by-step testing procedures, training videos, preferably
Languages of the training(s): English, French and Spanish/Portuguese, more preferably
Training material: Available in electronic format
Packaging photos: photo for kit components, primary and secondary packaging

REGULATORY / OTHER
Quality Management System (QMS): product and manufacturer must comply to ISO13485 or an equivalent QMS recognized by a regulatory authority of the founding members of the GHTF
Market approval certificate: product and manufacturer conform to European directive CE 98/79 IVD (or equivalent) (if available)
WHO Prequalification: PQ approval if available
Emergency listing: WHO EUAL and / or FDA EUA , if available
Hazardous classification: including Material Safety Data Sheets (MSDS).
ITEM  030
U481900   Various reagents

GENERAL DESCRIPTION
Another reagent(s) needed to run the items 010/020 but not listed before.

Product name(s): to be indicated by supplier
Technical specification(s): to be indicated by supplier

ITEM  040
U481900   Various consumables

GENERAL DESCRIPTION
Another consumable(s) needed to run the items 010/020 but not listed before.

Product name(s): to be indicated by supplier
Technical specification(s): to be indicated by supplier

ITEM  050
U481900   Various devices

GENERAL DESCRIPTION
Another device(s) needed to run the items 010/020 but not listed before.

Product name(s): to be indicated by supplier
Technical specification(s): to be indicated by supplier
Schedule 2: RDT antigen (Ag) detection technology

ITEM 060

U481900 ZIKV RDT Ag detection test

GENERAL DESCRIPTION
Single use disposable ZIKV rapid serology to detect ZIKV specific antigen(s) (Ag)

INTENDED USE
Screening/ surveillance of pregnant women for acute ZIKV infection at point-of-care

GENERAL SPECIFICATIONS
Product technology status: Design freeze stage/lockdown
Format: Single use disposable rapid test
Principle of assay: Rapid serology assay to detect ZIKV specific antibodies (IgM and/or IgG)
Type of result: Qualitative
Intended testing population: Pregnant women and sexual partners
Intended user of the test: Health care worker at point-of-care
Intended setting of use: point-of-care (Primary Health Care Level). Suitable for outreach/ resource limited settings
Output: Detection of ZIKV specific Ag(s)

ASSAY PERFORMANCE
Limit of detection: lowest detectable concentration of ZIKV at approx. 95% of replicates test positive
Sensitivity: minimum > 85% for specific ZIKV Ag
Specificity: minimum > 85% for specific ZIKV Ag
Analytical specificity- cross reactivity: Evaluated and show no significant cross reactivity against Dengue (from primary and secondary infections), Yellow Fever vaccination, Chikungunya, West Nile virus
Analytical specificity-Interference substances: Evaluated over the expected clinical range of the potential interfering substance
Inclusivity: performance with different strains, using specimens sourced globally
Clinical Evidence (diagnostic sensitivity and specificity): provide details of the clinical evaluation study including:
* 50 confirmed positive ZIKV clinical specimens
* 25 specified from pregnant women from affected area
* 100 specimen with confirmed negative ZIKV / negative other arbovirus infections
* 25-50 specimen from individuals in target area for use of the assay
Technical file: include in addition to the herein mentioned technical specifications: product design, its workflow, Analytical and clinical studies for validation and verification of the test, field testing studies (accuracy and correlation with applicable standards, and its clinical effectiveness, robustness of the technology in low-income country environments), repeatability and reproducibility of results (addressing if any lot variations), any assay limitations....

ASSAY IN PRACTICE
Specimen type used for analysis: Capillary finger-prick- blood/ whole blood
Specimen volume used for analysis: Approx. 20ul
Time to get a result: Approx. 20 min (from specimen collection to test result)
Interpretation of the results: Visually
Rapid test kit components: Rapid test kit contains all necessary reagents to complete ZIKV specific Ag from specimen collection to test-result
Internal quality control: Built-in quality positive and negative control lines
Temperature during transport: Approx. 10 - 35°C
Operating temperature and storage: Approx. 10 - 35°C
Operating relative humidity: Approx. 10 - 90% non-condensing
Shelf life for unopened test and buffer solution: Minimum 6 months, 12 months preferably
Shelf for opened tests and buffer solution:
  Test strip/ cartridge: use immediately after opening pouch containing single-use test.
  Buffer solution: minimum 6 months

EASE OF USE
Product operational procedure: Around 3-5 steps from specimen collection to producing a test result, preferably
Languages of the Instructions for use (IFU): English, French and Spanish/Portuguese, more preferably
Level of education (cadre) to perform the test: All levels of health care workers
Health care system that fit the technology: From primary health care level upwards

ITEMS SUPPLIED WITH
Kit contains: The Packaging box, re-closable for safe storage and transportation is supplied minimum with the following items:
  · Single use disposable rapid tests;
  · Blood transfer devices;
  · Disinfection swabs;
  · Safety lancets;
  · Buffer solution;
  · Instructions for use in English, French and Spanish/Portuguese."
Other items supplied with: Indicate other items the product is supplied with, apart from the ones mentioned above
Sizes of the test kit box: Indicate all the pack sizes available for this product

ACCESSORIES
Accessories, and other products that are intended to be used in combination with the IVD but are not provided: none

TRAINING/PRODUCT PHOTO
Type of training(s) offered to customers: no or minimal user training
Training material available to customers: Training poster, pictogram-based step-by-step testing procedures, training videos, preferably
Languages of the training(s): English, French and Spanish/Portuguese, more preferably
Training material: Available in electronic format
Packaging photos: photo for kit components, primary and secondary packaging

REGULATORY / OTHER
Quality Management System (QMS): product and manufacturer must comply to ISO13485 or an equivalent QMS recognized by a regulatory authority of the founding members of the GHTF
Market approval certificate: product and manufacturer conform to European directive CE 98/79 IVD (or equivalent) (if available)
WHO Prequalification: PQ approval if available
Emergency listing: WHO EUAL and / or FDA EUA , if available
Hazardous classification: including Material Safety Data Sheets (MSDS).
ITEM 070

U481900 Multiplex (ZIKV / X Arbovirus) RDT Ag detection test

GENERAL DESCRIPTION
Single use disposable ZIKV rapid serology to simultaneously detect ZIKV / X Arbovirus (Dengue virus DENV and/or Chikungunya virus CHKNV and/or Yellow fever virus YF and/or West Nile Virus WNV) specific antigen(s)

INTENDED USE
Screening/surveillance of pregnant women for acute ZIKV infection at point-of-care

GENERAL SPECIFICATIONS
Product technology status: Design freeze stage/lockdown
Format: Single use disposable rapid test
Principle of assay: Rapid serology assay to detect simultaneously detect ZIKV / X Arbovirus (Dengue virus DENV and/or Chikungunya virus CHKNV and/or Yellow fever virus YF and/or West Nile Virus WNV) specific antigen(s)
Type of result: Qualitative
Intended testing population: Pregnant women and sexual partners
Intended user of the test: Health care worker at point-of-care
Intended setting of use: point-of-care (Primary Health Care Level). Suitable for outreach/resource limited settings
Output: Simultaneous detection of ZIKV specific Ag(s) and/or DENV specific Ag and/or CHKNV specific Ag and/or YF specific Ag and/or WNV specific Ag

ASSAY PERFORMANCE
Limit of detection: lowest detectable concentration of ZIKV/ X arbovirus (DENV/CHKNV/YF/WNV) for each virus claimed to be detected at approx. 95% of replicates test positive
Sensitivity: minimum > 85% for specific ZIKV Ag/ X Arbovirus Ag
Specificity: minimum > 85% for specific ZIKV Ag/ X Arbovirus Ag
Analytical specificity- cross reactivity: Evaluated and show no significant cross reactivity against Dengue (from primary and secondary infections), Yellow Fever vaccination, Chikungunya, West Nile virus
Analytical specificity-Interference substances: Evaluated over the expected clinical range of the potential interfering substance
Inclusivity: performance with different strains, using specimens sourced globally
Clinical Evidence (diagnostic sensitivity and specificity): provide details of the clinical evaluation study including:
* 50 confirmed positive ZIKV clinical specimens
* 25 specified from pregnant women from affected area
* 100 specimen with confirmed negative ZIKV / negative other arbovirus infections
* 25-50 specimen from individuals in target area for use of the assay
Technical file: include in addition to the herein mentioned technical specifications: product design, its workflow, Analytical and clinical studies for validation and verification of the test, field testing studies (accuracy and correlation with applicable standards, and its clinical effectiveness, robustness of the technology in low-income country environments), repeatability and reproducibility of results (addressing if any lot variations), any assay limitations...
ASSAY IN PRACTICE
Specimen type used for analysis: Capillary finger-prick- blood/ whole blood
Specimen volume used for analysis: Approx. 20ul
Time to get a result: Approx. 20 min (from specimen collection to test result)
Interpretation of the results: Visually
Rapid test kit components: Rapid test kit contains all necessary reagents to complete Multiplex (ZIKV /X arbovirus) specific Ag from specimen collection to test-result
Internal quality control: Built-in quality positive and negative control lines
Temperature during transport: Approx. 10 - 35°C
Operating temperature and storage: Approx. 10 - 35°C
Operating relative humidity: Approx. 10 - 90% non-condensing
Shelf life for unopened test and buffer solution: Minimum 6 months, 12 months preferably
Shelf for opened tests and buffer solution:
  Test strip/ cartridge: use immediately after opening pouch containing single-use test.
  Buffer solution: minimum 6 months

EASE OF USE
Product operational procedure: Around 3-5 steps from specimen collection to producing a test result, preferably
Languages of the Instructions for use (IFU): English, French and Spanish/Portuguese, more preferably
Level of education (cadre) to perform the test: All levels of health care workers
Health care system that fit the technology: From primary health care level upwards

ITEMS SUPPLIED WITH
Kit contains: The Packaging box, re-closable for safe storage and transportation is supplied minimum with the following items:
  · Single use disposable rapid tests;
  · Blood transfer devices;
  · Disinfection swabs;
  · Safety lancets;
  · Buffer solution;
  · Instructions for use in English, French and Spanish/Portuguese."
Other items supplied with: Indicate other items the product is supplied with, apart from the ones mentioned above
Sizes of the test kit box: Indicate all the pack sizes available for this product

ACCESSORIES
Accessories, and other products that are intended to be used in combination with the IVD but are not provided: none

TRAINING/PRODUCT PHOTO
Type of training(s) offered to customers: no or minimal user training
Training material available to customers: Training poster, pictogram-based step-by-step testing procedures, training videos, preferably
Languages of the training(s): English, French and Spanish/Portuguese, more preferably
Training material: Available in electronic format
Packaging photos: photo for kit components, primary and secondary packaging

REGULATORY / OTHER

Quality Management System (QMS): product and manufacturer must comply to ISO13485 or an equivalent QMS recognized by a regulatory authority of the founding members of the GHTF

Market approval certificate: product and manufacturer conform to European directive CE 98/79 IVD (or equivalent) (if available)

WHO Prequalification: PQ approval if available

Emergency listing: WHO EUAL and / or FDA EUA, if available

Hazardous classification: including Material Safety Data Sheets (MSDS).
ITEM  080

U481900 Various reagents

**GENERAL DESCRIPTION**
Another reagent(s) needed to run the items 060/070 but not listed before.

*Product name(s):* to be indicated by supplier

*Technical specification(s):* to be indicated by supplier

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ITEM  090

U481900 Various consumables

**GENERAL DESCRIPTION**
Another consumable(s) needed to run the items 060/070 but not listed before

*Product name(s):* to be indicated by supplier

*Technical specification(s):* to be indicated by supplier

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ITEM  100

U481900 Various devices

**GENERAL DESCRIPTION**
Another device(s) needed to run the items 060/070 but not listed before.

*Product name(s):* to be indicated by supplier

*Technical specification(s):* to be indicated by supplier
Schedule 3: POC nucleic acid testing (NAT) technology

ITEM 110
U481900 ZIKV POC NAT

GENERAL DESCRIPTION
Single use POC test with reader device to detect ZIKV specific RNA

INTENDED USE
Screening/surveillance of pregnant women for acute ZIKV infection at point-of-care

GENERAL SPECIFICATIONS
Product technology status: Design freeze stage/lockdown
Format: Single use POC test with reader device
Principle of assay: Able to provide equivalency to gold standard RT-PCR detection of ZIKV viral RNA
Type of result: Qualitative
Intended testing population: Pregnant women and sexual partners
Intended user of the test: Health care worker at point-of-care
Intended setting of use: point-of-care (Primary Health Care Level). Suitable for outreach/resource limited settings
Output: Detection of ZIKV specific RNA

ASSAY PERFORMANCE
Limit of detection: <500 copies / ml
Sensitivity: minimum > 85% for specific ZIKV RNA
Specificity: minimum > 85% for specific ZIKV RNA
Analytical specificity-cross reactivity: Evaluated and show no significant cross reactivity against Dengue (from primary and secondary infections), Yellow Fever vaccination, Chikungunya, West Nile virus
Analytical specificity-Interference substances: Evaluated over the expected clinical range of the potential interfering substance
Inclusivity: performance with different strains, using specimens sourced globally
Clinical Evidence (diagnostic sensitivity and specificity): provide details of the clinical evaluation study including:
* 50 confirmed positive ZIKV clinical specimens
* 25 specified from pregnant women from affected area
* 100 specimen with confirmed negative ZIKV / negative other arbovirus infections
* 25-50 specimen from individuals in target area for use of the assay
Technical file: include in addition to the herein mentioned technical specifications: product design, its workflow, Analytical and clinical studies for validation and verification of the test, field testing studies (accuracy and correlation with applicable standards, and its clinical effectiveness, robustness of the technology in low-income country environments), repeatability and reproducibility of results (addressing if any lot variations), any assay limitations....

ASSAY IN PRACTICE
Specimen type used for analysis: Capillary finger-prick- blood/ whole blood
Specimen volume used for analysis: Approx. 30ul
**Time to get a result**: Approx. 20 min (from specimen collection to test result)

**POC test kit components**: POC test kit contains all necessary reagents to complete ZIKV specific RNA from specimen collection to test-result

**Interpretation of the results**: with the support of a hand-held device (equipment)

**Cartridge**
- **Reagents**: Contains all necessary reagents to complete detection of ZIKV RNA, from whole blood sample to test-result
- **Shelf life for unopened test and buffer solution**: Minimum 6 months, 12 months preferably
- **Shelf for opened tests and buffer solution**:
  - Test strip/cartridge: use immediately after opening pouch containing single-use test
  - Buffer solution: minimum 6 months

**Equipment**
- Portable table top counter; light equipment. Factory calibrated and built-in auto-self-test, each time the device is switched-on.
  - **Calibration**: Factory calibrated and built-in auto-self-test, each time the device is switched-on. Please explain calibration of product
  - **Throughput**: number of samples per operator per day (8 hours working day) need to be advised by supplier
- **Printer**: Built-in printer able to print out test result, patient ID, date, quality control results, preferably.
- **Thermal paper for running the printer**: number of tests results printed with 1 roll of thermal paper need to be advised by supplier
- **Reports on the screen and print out**: details of report need to be advised by supplier
  - **Language screen display**: user selectable: English, French and Spanish/Portuguese.
  - **Information displayed on the screen**: Large backlit alphanumeric display (LCD) informs:
    - Device operational status and on-going analysis
    - Measured results in cells/ul, per patient ID, with date and time
    - System errors or malfunctions, incl. insufficient sample volume
    - Status built-in battery
  - **Design of cartridge**: insertion port, eliminates all likelihood of sample cross-contamination
- **Data storage**: capacity of storage test results of approx. 100 test results, more preferably.
- **Connectivity**: Built-in network connection card DCOM, USB port, Ethernet or equivalent, preferably
- **Power requirements**: Built-in battery and 100-240 V / 50 Hz
- **Power consumption**: of approx.: 20 Watts.
- **Voltage surge protection**: Built-in voltage surge protection, preferably
- **Capacity battery life**: built-in rechargeable battery, preferably
- **Alternative charging options**: solar panel, car battery, etc.
- **Internal quality control**: Built-in quality positive and negative control lines
- **Temperature during transport**: Approx. 10 - 35°C
- **Operating temperature and storage**: Approx. 10 - 35°C
- **Operating relative humidity**: Approx. 10 - 90% non-condensing

**EASE OF USE**
- **Product operational procedure**: Around 3-5 steps from specimen collection to producing a test result, preferably
- **Languages of the Instructions for use (IFU)**: English, French and Spanish/Portuguese, more preferably
- **Level of education (cadre) to perform the test**: All levels of health care workers
Health care system that fit the technology: From primary health care level upwards

ITEMS SUPPLIED WITH
Kit contains: The Packaging box, re-closable for safe storage and transportation is supplied minimum with the following items:
- Single use disposable rapid tests;
- Blood transfer devices;
- Disinfection swabs;
- Safety lancets;
- Buffer solution;
- Instructions for use in English, French and Spanish/Portuguese."

Other items supplied with: Indicate other items the product is supplied with, apart from the ones mentioned above
Sizes of the test kit box: Indicate all the pack sizes available for this product

ACCESSORIES
Accessories, and other products that are intended to be used in combination with the IVD but are not provided: none

TRAINING/PRODUCT PHOTO
Type of training(s) offered to customers: no or minimal user training
Training material available to customers: Training poster, pictogram-based step-by-step testing procedures, training videos, preferably
Languages of the training(s): English, French and Spanish/Portuguese, more preferably
Training material: Available in electronic format
Packaging photos: photo for kit components, primary and secondary packaging

REGULATORY / OTHER
Quality Management System (QMS): product and manufacturer must comply to ISO13485 or an equivalent QMS recognized by a regulatory authority of the founding members of the GHTF
Market approval certificate: product and manufacturer conform to European directive CE 98/79 IVD (or equivalent) (if available)
WHO Prequalification: PQ approval if available
Emergency listing: WHO EUAL and / or FDA EUA , if available
Hazardous classification: including Material Safety Data Sheets (MSDS),
ITEM 120
U481900 Multiplex (ZIKV/ X Arbovirus) POC NAT

GENERAL DESCRIPTION
Single use POC test with reader device for simultaneous detection of ZIKV viral RNA with other related arbovirus RNA (DENV and/or CHKNV and/or YF and/or WNV)

INTENDED USE
Screening/ surveillance of pregnant women for acute ZIKV infection at point-of-care

GENERAL SPECIFICATIONS
Product technology status: Design freeze stage/lockdown
Format: Single use POC test with reader device
Principle of assay: Able to provide equivalency to gold standard RT-PCR detection of ZIKV viral RNA
Type of result: Qualitative
Intended testing population: Pregnant women and sexual partners
Intended user of the test: Health care worker at point-of-care
Intended setting of use: point-of-care (Primary Health Care Level). Suitable for outreach/ resource limited settings
Output: simultaneous detection of ZIKV viral RNA with other related arbovirus RNA (DENV and/or CHKNV and/or YF and/or WNV)

ASSAY PERFORMANCE
Limit of detection: <500 copies / ml (ZIKV viral RNA with other related arbovirus RNA (DENV and/or CHKNV and/or YF and/or WNV) for each virus claimed to be detected at approx. 95% of replicates test positive
Sensitivity: minimum > 85% for specific ZIKV RNA/ X Arbovirus RNA
Specificity: minimum > 85% for specific ZIKV RNA/ X Arbovirus RNA
Analytical specificity-cross reactivity: Evaluated and show no significant cross reactivity against Dengue (from primary and secondary infections), Yellow Fever vaccination, Chikungunya, West Nile virus
Analytical specificity-Interference substances: Evaluated over the expected clinical range of the potential interfering substance
Inclusivity: performance with different strains, using specimens sourced globally
Clinical Evidence (diagnostic sensitivity and specificity): provide details of the clinical evaluation study including:
* 50 confirmed positive ZIKV clinical specimens
* 25 specified from pregnant women from affected area
* 100 specimen with confirmed negative ZIKV / negative other arbovirus infections
* 25-50 specimen from individuals in target area for use of the assay
Technical file: include in addition to the herein mentioned technical specifications: product design, its workflow, Analytical and clinical studies for validation and verification of the test, field testing studies (accuracy and correlation with applicable standards, and its clinical effectiveness, robustness of the technology in low-income country environments), repeatability and reproducibility of results (addressing if any lot variations), any assay limitations....

ASSAY IN PRACTICE
Specimen type used for analysis: Capillary finger-prick- blood/ whole blood
Specimen volume used for analysis: Approx. 30ul
Time to get a result: Approx. 20 min (from specimen collection to test result)
POC test kit components: POC test kit contains all necessary reagents to complete ZIKV specific RNA from specimen collection to test-result
Interpretation of the results: with the support of a hand-held device (equipment)
Cartridge
Reagents: Contains all necessary reagents to complete detection of ZIKV viral RNA with other related arbovirus RNA (DENV and/or CHKNV and/or YF and/or WNV, from whole blood sample to test-result
Shelf life for unopened test and buffer solution: Minimum 6 months, 12 months preferably
Shelf for opened tests and buffer solution:
  Test strip/ cartridge: use immediately after opening pouch containing single-use test
  Buffer solution: minimum 6 months

Equipment
Portable table top counter; light equipment. Factory calibrated and built-in auto-self-test, each time the device is switched-on.
Calibration Factory calibrated and built-in auto-self-test, each time the device is switched-on. Please explain calibration of product
Throughput: number of samples per operator per day (8 hours working day) need to be advised by supplier
Printer: Built-in printer able to print out test result, patient ID, date, quality control results, preferably.
Thermal paper for running the printer: number of tests results printed with 1 roll of thermal paper need to be advised by supplier
Reports on the screen and print out: details of report need to be advised by supplier
Language screen display: user selectable: English, French and Spanish/Portuguese.
Information displayed on the screen: Large backlit alphanumeric display (LCD) informs:
  - Device operational status and on-going analysis
  - Measured results in cells/ul, per patient ID, with date and time
  - System errors or malfunctions, incl. insufficient sample volume
  - Status built-in battery”
Design of cartridge: insertion port, eliminates all likelihood of sample cross-contamination
Data storage: capacity of storage test results of approx. 100 test results, more preferably.
Connectivity: Built-in network connection card DCOM, USB port, Ethernet or equivalent, preferably
Power requirements: Built-in battery and 100-240 V / 50 Hz
Power consumption: of approx.: 20 Watts.
Voltage surge protection: Built-in voltage surge protection, preferably
Capacity battery life: built-in rechargeable battery, preferably
Alternative: charging options: solar panel, car battery, etc.
Internal quality control: Built-in quality positive and negative control lines
Temperature during transport: Approx. 10 - 35°C
Operating temperature and storage: Approx. 10 - 35°C
Operating relative humidity: Approx. 10 - 90% non-condensing

EASE OF USE
Product operational procedure: Around 3-5 steps from specimen collection to producing a test result, preferably
Languages of the Instructions for use (IFU): English, French and Spanish/Portuguese, more preferably
Level of education (cadre) to perform the test: All levels of health care workers
Health care system that fit the technology: From primary health care level upwards

ITEMS SUPPLIED WITH
Kit contains: The Packaging box, re-closable for safe storage and transportation is supplied minimum with the following items:
· Single use disposable rapid tests;
· Blood transfer devices;
· Disinfection swabs;
· Safety lancets;
· Buffer solution;
· Instructions for use in English, French and Spanish/Portuguese.

Other items supplied with: Indicate other items the product is supplied with, apart from the ones mentioned above
Sizes of the test kit box: Indicate all the pack sizes available for this product

ACCESSORIES
Accessories, and other products that are intended to be used in combination with the IVD but are not provided: none

TRAINING/PRODUCT PHOTO
Type of training(s) offered to customers: no or minimal user training
Training material available to customers: Training poster, pictogram-based step-by-step testing procedures, training videos, preferably
Languages of the training(s): English, French and Spanish/Portuguese, more preferably
Training material: Available in electronic format
Packaging photos: photo for kit components, primary and secondary packaging

REGULATORY / OTHER
Quality Management System (QMS): product and manufacturer must comply to ISO13485 or an equivalent QMS recognized by a regulatory authority of the founding members of the GHTF
Market approval certificate: product and manufacturer conform to European directive CE 98/79 IVD (or equivalent) (if available)
WHO Prequalification: PQ approval if available
Emergency listing: WHO EUAL and / or FDA EUA , if available
Hazardous classification: including Material Safety Data Sheets (MSDS).
ITEM 130

U481900 Various reagents

GENERAL DESCRIPTION
Another reagent(s) needed to run the items 110/120 but not listed before.

Product name(s): to be indicated by supplier

Technical specification(s): to be indicated by supplier

ITEM 140

U481900 Various consumables

GENERAL DESCRIPTION
Another consumable(s) needed to run the items 110/120 but not listed before.

Product name(s): to be indicated by supplier

Technical specification(s): to be indicated by supplier

ITEM 150

U481900 Various devices

GENERAL DESCRIPTION
Another device(s) needed to run the items 110/120 but not listed before.

Product name(s): to be indicated by supplier

Technical specification(s): to be indicated by supplier
Schedule 4: ZIKV RDT/POC IVD technologies other than mentioned under schedule 1-3

ITEM 160

U481900 ZIKV RDT/POC IVD test

GENERAL DESCRIPTION
Single use disposable ZIKV rapid test/POC for the detection of ZIKV specific Ab (IgM and/or IgG) and/or ZIKV specific Ag and/or ZIKV RNA in single and/or multiplex format

INTENDED USE
Screening/surveillance of pregnant women for acute ZIKV infection at point-of-care

GENERAL SPECIFICATIONS
Product technology status: Design freeze stage/lockdown
Format: Single use disposable RDT/POC
Principle of assay: To be described by supplier
Type of result: Qualitative
Intended testing population: Pregnant women and sexual partners
Intended user of the test: Health care worker at point-of-care
Intended setting of use: point-of-care (Primary Health Care Level). Suitable for outreach/ resource limited settings
Output: to be specified by the supplier

ASSAY PERFORMANCE
Sensitivity: minimum > 85%
Specificity: minimum > 85%
Analytical specificity-cross reactivity: Evaluated and show no significant cross reactivity against Dengue (serotypes 1-4 both from primary and secondary infections), Yellow Fever vaccination, Chikungunya, West Nile virus
Analytical specificity-Interference substances: Evaluated over the expected clinical range of the potential interfering substance
Clinical Evidence (diagnostic sensitivity and specificity): provide details of the clinical evaluation study including:
* 50 confirmed positive ZIKV clinical specimens
* 50 specified from pregnant women from affected area
* 50-100 specimen with confirmed negative ZIKV / negative other arbovirus infections
* 25-50 specimen from individuals in target area for use of the assay
* using specimens sourced globally"
Technical file: include in addition to the herein mentioned technical specifications: product design, its workflow, Analytical and clinical studies for validation and verification of the test, field testing studies (accuracy and correlation with applicable standards, and its clinical effectiveness, robustness of the technology in low-income country environments), repeatability and reproducibility of results (addressing if any lot variations), any assay limitations....

ASSAY IN PRACTICE
Specimen type used for analysis: Capillary finger-prick! blood/whole blood
Specimen volume used for analysis: To be described by supplier
Time to get a result: To be described by supplier
Interpretation of the results: To be described by supplier
Rapid test kit components: To be described by supplier
Internal quality control: To be described by supplier
Temperature during transport: To be described by supplier
Operating temperature and storage: To be described by supplier
Operating relative humidity: To be described by supplier
Shelf life for unopened test and buffer solution: To be described by supplier
Shelf for opened tests and buffer solution: To be described by supplier

EASE OF USE
Product operational procedure: Around 3-5 steps from specimen collection to producing a test result, preferably
Languages of the Instructions for use (IFU): English, French and Spanish/Portuguese, more preferably
Level of education (cadre) to perform the test: All levels of health care workers
Health care system that fit the technology: From primary health care level upwards

ITEMS SUPPLIED WITH
Kit contains: to be described by supplier
Other items supplied with: to be described by supplier
Sizes of the test kit box: to be described by supplier

ACCESSORIES
Accessories, and other products that are intended to be used in combination with the IVD but are not provided: to be described by supplier

TRAINING/PRODUCT PHOTO
Type of training(s) offered to customers: no or minimal user training
Training material available to customers: Training poster, pictogram-based step-by-step testing procedures, training videos, preferably
Languages of the training(s): English, French and Spanish/Portuguese, more preferably
Training material: Available in electronic format
Packaging photos: photo for kit components, primary and secondary packaging

REGULATORY / OTHER
Quality Management System (QMS): product and manufacturer must comply to ISO13485 or an equivalent QMS recognized by a regulatory authority of the founding members of the GHTF
Market approval certificate: product and manufacturer conform to European directive CE 98/79 IVD (or equivalent) (if available)
WHO Prequalification: PQ approval if available
Emergency listing: WHO EUAL and / or FDA EUA , if available
Hazardous classification: including Material Safety Data Sheets (MSDS),