Product code (or CDC identification):	**Manufacturer:**
Technician name:	**Technician ID:**

NOTE: Questions in yellow are aimed to be addressed by/after manufacturers

- LABELING –

I . Labeling of the RDT Box:

		Reply	Comments	*Additional info:*
A.	**General box labeling requirements:**			
[1]	*Labeling is printed on the cardboard as **permanent printing** OR applied as **water-resistant labels** (with water-resistant glue)?*	Y ( ) N ( )	*CDC may add observations if applicable:*	***TO BE COMPLETED BY MANUFACTURER***
2	If symbols are used, are all of them **internationally recognized symbols**?	Y ( ) N ( ) P ( ) NA ( )		(EN ISO 15223 – 2012 or, if applicable, the *globally harmonized system of classification and labelling of chemicals*) See **Box 1 a-b** in the Annex (AID)
3	Does the **box labeling** comply with the **minimum** standards for legibility (text size and spacing)?	Y ( ) N ( )		*i.e.* Characters of at least 7 points, or of a size where the lower case "x" is at least 1.4mm in height // Interline spacing at least 3mm. Refer to **Box 2** in the Annex (AID) for a text example – [A]
4	Does the **box labeling** align with the **recommended** standards for optimal font and text size?	H ( ) M ( ) L ( )		Refer to **Box 2** in the Annex (AID) for text examples – [B]
[5]	*Packaging of this product is available in other **languages** relevant to the region where the product is used?*	*Y ( ) N ( )*	*Specify languages:*	***TO BE COMPLETED BY MANUFACTURER***
→	Does the **product name** include:			
6	Commercial name of the product?	Y ( ) N ( )		Example: Commercial name, Malaria Pf/Pv (HRP2/pLDH) Antigen(RDT)
7	"Malaria"?	Y ( ) N ( )		
8	"Antigen" or "Ag"?	Y ( ) N ( )		
9	Targeted species: *Pf, Pan...?*	Y ( ) N ( )		
10	Targeted antigen/s: *HRP2, pLDH...?*	Y ( ) N ( )		
11	Does the full name provide sufficient detail to uniquely identify the product?	Y ( ) N ( )		

Y=yes; N=no; NA=not applicable; P=partially; H=high; M=medium; L=low

B.	**What is displayed on the box:**			
12	**Product name**?	Y ( ) N ( ) P ( )		P: if name is displayed but does not include all terms listed in Q7-Q11
13	**Product code** (and symbol)?	Y ( ) N ( ) P ( )		*i.e.* catalogue number P: if symbol is missing
14	**Intended use**?	Y ( ) N ( ) P ( )		At least, diagnosis of malaria, *in vitro* diagnostic, professional-use. The product full name can already include part of the intended use description.
15	**Number of tests** provided in the kit (and symbol)?	Y ( ) N ( ) P ( )		
16	"***In vitro* diagnostic**" (or symbol)?	Y ( ) N ( )		
17	**Name** of the **legal manufacturer**?	Y ( ) N ( )		
18	**Physical address** of the manufacturing site?	Y ( ) N ( )		
19	**Telephone** and/or **fax** number and/or **website** of the manufacturer?	Y ( ) N ( )		
20	**Lot number** (and symbol)?	Y ( ) N ( ) P ( )		
21	**Expiration date** (and symbol)?	Y ( ) N ( ) P ( )		
22	Is the expiration date displayed in this format: **YYYY-MM**?	Y ( ) N ( ) NA ( )		
23	**Contents of the box** (materials provided)?	Y ( ) N ( ) P ( )		Indicate which ones not included
24	**Quantity** of materials provided?	Y ( ) N ( ) P ( )		Indicate which ones not included
25	Items required but **not provided**?	Y ( ) N ( ) P ( )		At least: gloves, biosafety sharps container, biohazard waste container, timer, pencil/pen. Indicate which ones not included
26	**Storage conditions** (symbols)?	Y ( ) N ( ) P ( )		At least: Storage temperature range & "*Keep dry*" symbols.
27	**Warnings** or **precautions** (symbols)?	Y ( ) N ( ) P ( )		At least: *"Do not use if packaging is damaged" & "Read instructions before use"* symbols. "*Biohazard*" symbol, if applicable (*e.g.* buffer sodium azide concentration ≥0.1%; desiccant contains cobalt chloride)
[28]	*Have the procedure or IFU **changed substantially** since the last version of the product?*	*Y ( ) N ( )*		***TO BE COMPLETED BY MANUFACTURER***
[29]	*If the procedure or IFU has changed substantially, is there an **additional warning** with a clearly **visible label**?*	*Y ( ) N ( ) NA ( )*	*CDC may add observations if applicable:*	*e.g.* fluorescent orange ***TO BE COMPLETED AFTER MANUFACTURER'S FEEDBACK***
[30]	*If an **additional warning** is displayed, does it include information about the **change** and **effective date**?*	*Y ( ) N ( )* *P ( ) NA ( )*	*CDC may add observations if applicable:*	***TO BE COMPLETED AFTER MANUFACTURER'S FEEDBACK***
C.	**Where is the box information displayed:**			
→	Information displayed on the <u>top of the RDT box</u>:			See convention of terms in the Annex (AID) – ***Figure 1***
31	Product name?	Y ( ) N ( ) P ( ) NA ( )		Check alignment with ***Figure 2*** model in the Annex (AID).
32	Intended use?	Y ( ) N ( ) P ( ) NA ( )		NA = when the information is not displayed in the box, according to replies in section B

Y=yes; N=no; NA=not applicable; P=partially; H=high; M=medium; L=low

33	Product code?	Y ( ) N ( ) NA ( )		
34	Number of tests provided in the kit?	Y ( ) N ( ) NA ( )		
35	Lot number?	Y ( ) N ( ) NA ( )		
36	Expiration date?	Y ( ) N ( ) NA ( )		
37	Manufacturer details?	Y ( ) N ( ) P ( ) NA ( )		
38	"*Keep dry*" (symbol)?	Y ( ) N ( ) NA ( )		
39	Storage temperature range (symbol)?	Y ( ) N ( ) NA ( )		
→	Information displayed on the <u>front side of the RDT box</u>:			See convention of terms in the Annex (AID) – ***Figure 1***
40	Product name?	Y ( ) N ( ) P ( ) NA ( )		Check alignment with ***Figure 3*** model in the Annex (AID).
41	Product code?	Y ( ) N ( ) NA ( )		
42	Number of tests provided in the kit?	Y ( ) N ( ) NA ( )		
43	Lot number?	Y ( ) N ( ) NA ( )		
44	Expiration date?	Y ( ) N ( ) NA ( )		
[45]	*"Sterile"?*	Y ( ) N ( ) NA ( )		***TO BE COMPLETED AFTER MANUFACTURER'S FEEDBACK***
[46]	*Sterilization method (symbol)?*	Y ( ) N ( ) NA ( )		
47	Contents of the box and quantities (materials provided)?	Y ( ) N ( ) P ( ) NA ( )		Check alignment with ***Figure 3*** model in the Annex (AID).
48	Items required but not provided?	Y ( ) N ( ) P ( ) NA ( )		
49	"*Keep dry*" (symbol)?	Y ( ) N ( ) NA ( )		
50	Storage temperature range (symbol)?	Y ( ) N ( ) NA ( )		
→	Information displayed on at least one <u>lateral side of the RDT box</u>:			See convention of terms in the Annex (AID) – ***Figure 1***
51	Product name?	Y ( ) N ( ) P ( ) NA ( )		Check alignment with ***Figure 3*** model in the Annex (AID).
52	Product code?	Y ( ) N ( ) NA ( )		
53	Number of tests provided in the kit?	Y ( ) N ( ) NA ( )		
54	Lot number?	Y ( ) N ( ) NA ( )		
55	Expiration date?	Y ( ) N ( ) NA ( )		
[56]	*"Sterile" and sterilization method symbol?*	Y ( ) N ( ) NA ( )		***TO BE COMPLETED AFTER MANUFACTURER'S FEEDBACK***
[57]	*Sterilization method (symbol)?*	Y ( ) N ( ) NA ( )		
58	Contents of the box and quantities (materials provided)?	Y ( ) N ( ) P ( ) NA ( )		Check alignment with ***Figure 3*** model in the Annex (AID).
59	Items required but not provided?	Y ( ) N ( ) P ( ) NA ( )		
60	"*Keep dry*" (symbol)?	Y ( ) N ( ) NA ( )		
61	Storage temperature range (symbol)?	Y ( ) N ( ) NA ( )		

Y=yes; N=no; NA=not applicable; P=partially; H=high; M=medium; L=low

II. Labeling of the cassette primary packaging:

		Reply	Comments	*Additional info:*
A.	**What is displayed on the cassette primary packaging:**			
62	**Product name**?	Y ( ) N ( ) P ( )		P (partially): if name is displayed but does not include all terms listed above
63	**For product code** (or symbol)?	Y ( ) N ( )		*i.e.* catalogue number
64	**Intended use**?	Y ( ) N ( ) P ( )		At least. diagnosis of malaria, *in vitro* diagnostic, professional-use only, point-of-care testing. The product full name can already include part of the intended use description.
65	"***In vitro* diagnostic**" (or symbol)?	Y ( ) N ( )		
66	**Name (or logo)** of the legal **manufacturer**?	Y ( ) N ( )		
67	**Lot number** (and symbol)?	Y ( ) N ( ) P ( )		
68	Is the lot number **identical** to the one displayed on the RDT box?	Y ( ) N ( ) NA ( )		
69	**Expiration date** (and symbol)?	Y ( ) N ( ) P ( )		
70	Is the expiration date displayed in this format: **YYYY-MM**?	Y ( ) N ( ) NA ( )		
71	Is the expiration date **identical** or **later** than the one displayed on the RDT box?	Y ( ) N ( ) NA ( )		
72	**Quantity of tests** per packaging (if more than one test)?	Y ( ) N ( ) NA ( )		
73	**Contents of the packaging*** (if sufficient space)?	Y ( ) N ( ) NA ( )		* Including desiccant
74	If contents are listed, **quantities** of each component are indicated?	Y ( ) N ( ) P ( ) NA ( )		
75	**Storage conditions** (symbols)?	Y ( ) N ( ) P ( )		At least: Storage temperature range & "*Keep dry*" symbols.
76	**Warnings** or **precautions** (symbols)?	Y ( ) N ( ) P ( )		At least: *"Do not use if packaging is damaged", "Read instructions before use"* & Single-use symbols.
B.	**Where is the cassette primary packaging information displayed:**			
77	Information on the cassette primary packaging displayed as: All **standard generic** information on one side, and **custom/variable** information (expiration date, lot number) on the opposite side?	H ( ) M ( ) L ( )		Check alignment with ***Figure 4*** model in the Annex (AID).

Y=yes; N=no; NA=not applicable; P=partially; H=high; M=medium; L=low

III. Labeling of the cassette:

		Reply	Comments	*Additional info:*
A.	**General cassette labeling requirements:**			
[78]	*Printing is done in **indelible ink** (instead of embossed characters in the cassette housing)?*	*Y ( ) N ( )*	*CDC may add observations if applicable:*	***TO BE COMPLETED BY MANUFACTURER***
79	Is all printing oriented **along the short axis** of the cassette?	Y ( ) N ( )		See convention of terms in the Annex (AID) – ***Figure 5***
80	Labeling is **legible**?	H ( ) M ( ) L ( )		*i.e.* open letter type, clear print Check alignment with labeling represented in ***Figure 5*** – Annex (AID)
81	Is there a **single** and **unequivocal reading legend** next to the reading window?	Y ( ) N ( )		
82	Is the **reading legend** at the **right** hand side of the reading window?	Y ( ) N ( )		
83	Is there **space** left in the cassette surface for writing **patient identification**?	Y ( ) N ( )		
84	Is the cassette surface made of a material on which it is **possible to write** with a standard ink pen or pencil?	Y ( ) N ( )		
B.	**What is displayed on the cassette:**			
85	**Product name** (with indication of “Malaria”, “Ag”, *Plasmodium* species and the antigens detected) or **logical abbreviation** (referenced in the IFU)?	Y ( ) N ( ) P ( )		
86	Are the specimen and buffer **wells** labeled?	Y ( ) N ( ) P ( )		If ‘Partially’, indicate which one is not labelled
87	Is the **sample well** named “1”, and the **buffer well** named “2”?	Y ( ) N ( ) P ( ) NA ( )		*i.e.* chronological order If ‘No’ or ‘Partially’, indicate how are they labelled
88	Does the reading legend indicate the ***Plasmodium* species** detected?	Y ( ) N ( )		
89	Do all **reading legend abbreviations** comply with the recommendations*?	Y ( ) N ( ) P ( ) NA ( )		**RECOMMENDED ABBREVIATIONS:* • C (=control) • Pf • Pv • Pan • Pvom

Y=yes; N=no; NA=not applicable; P=partially; H=high; M=medium; L=low

IV. Labeling of the buffer bottle

		Reply	Comments	*Additional info:*
A.	**General buffer labeling requirements:**			
[90]	*Labeling is in a **well-fixed water-resistant label** (applied with water resistant glue) OR permanent **indelible printing** (lasting the life span of the RDT product).*	*Y ( ) N ( )*	*CDC may add observations if applicable:*	***TO BE COMPLETED BY MANUFACTURER***
91	If symbols are used, are all of them **internationally recognized symbols**?	Y ( ) N ( ) P ( ) NA ( )		(EN ISO 15223 – 2012 or, if applicable, the *globally harmonized system of classification and labelling of chemicals*) See **Box 1 a-b** in the Annex (AID)
[92]	*Intended use is always displayed in an official **language** relevant to the region where the product is used?*	*Y ( ) N ( )*	*Specify languages:*	***TO BE COMPLETED BY MANUFACTURER***
B.	**What is displayed in the buffer bottle:** *[see **Figure 6** in the Annex (AID) for a proposal of Buffer labeling]*			
93	**Product name** providing sufficient detail to **identify the type of product** with which to use the buffer?	Y ( ) N ( )		*e.g.* Malaria RDT
94	**Product name** provides sufficient detail to **uniquely identify** the RDT product and its intended use?	Y ( ) N ( )		*e.g.* Commercial name, Malaria Ag - Pf/Pv (HRP2/pLDH) RDT
95	**Contents: Buffer**?	Y ( ) N ( )		
96	Does the label include a **reference code** that is also written on the RDT box and/or in the IFU?	Y ( ) N ( )		
97	Does the label include "**[For] product code** (or symbol)"?	Y ( ) N ( )		*i.e.* same code as the one identifying the RDT product
98	*"**In vitro** **diagnostic**"* (or symbol)?	Y ( ) N ( )		
99	**Name (or logo)** of the legal **manufacturer**?	Y ( ) N ( )		
100	**Volume** of contents or **number of examinations** that can be performed?	Y ( ) N ( )		
101	**Lot number** (and symbol)?	Y ( ) N ( ) P ( )		
102	**Expiration date** (and symbol)?	Y ( ) N ( ) P ( )		
103	Is the expiration date displayed in this format: **YYYY-MM**?	Y ( ) N ( ) NA( )		
104	Is the expiration date **identical** or **later** than the expiration date on the RDT box and cassette packaging?	Y ( ) N ( ) NA( )		
105	**Storage conditions** (symbols)?	Y ( ) N ( )		At least: Storage temperature range
106	**Warnings** or **precautions** (symbols)?	Y ( ) N ( ) P( )		At least: *"Do not use if packaging is damaged", "Read instructions before use"* and "*Biohazard*" symbol (if buffer sodium azide concentration ≥0.1%)

Y=yes; N=no; NA=not applicable; P=partially; H=high; M=medium; L=low

V. Labeling of the accessories: transfer devices, lancets, alcohol swabs and desiccant

A.	General requirements for labeling of accessories:	Transfer device [a]	Lancet [b]	Alcohol swab [c]	Desiccant [d]	Comments
107	***ACCESSORY included in the kit?***	Y N ☐ ☐ ↓	Y N ☐ ☐ ↓	Y N ☐ ☐ ↓	Y N ☐ ☐ ↓	If YES, reply the questions in the column below (117-140). If NO, omit the questions for this accessory.
[108]	*Is labeling printed on the accessory (or its packaging) as **permanent indelible printing** OR applied as **water-resistant label** (with water resistant glue)?*	*Y ( ) N ( ) NA ( )* *[volume mark]*	*Y ( ) N ( )*	*Y ( ) N ( )*	*Y ( ) N ( )*	***TO BE COMPLETED BY MANUFACTURER***
109	If symbols are used, are all of them **internationally recognized symbols***?	Y ( ) N ( ) P ( ) NA ( )	Y ( ) N ( ) P ( ) NA ( )	Y ( ) N ( ) P ( ) NA ( )	Y ( ) N ( ) P ( ) NA ( )	
[110]	*Intended use is always displayed in an official **language** relevant to the region where the product is used?*	*Y ( ) N ( )*	*Y ( ) N ( )*	*Y ( ) N ( )*	*Y ( ) N ( )*	***TO BE COMPLETED BY MANUFACTURER***

*EN ISO 15223 – 2012 or, if applicable, the *globally harmonized system of classification and labelling of chemicals*. See Box 1 a-b in the Annex (AID)

B.	What is displayed on the accessories or on their packaging:	Transfer device [a]	Lancet [b]	Alcohol swab [c]	Desiccant [d]	Comments
	ACCESSORY included in the kit?	Y ☐ N ☐ ↓	Y ☐ N ☐ ↓	Y ☐ N ☐ ↓	Y ☐ N ☐ ↓	If YES, reply the questions in the column below (117-140). If NO, omit the questions for this accessory.
111	**Name** of accessory	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	
112	**Intended use** (sufficient to identify the device and its intended use: *e.g.* transfer device, antiseptic, desiccant)*	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	
113	Name of the legal **manufacturer** of the **accessory**	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	
114	Name of the **RDT manufacturer**	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	
115	For alcohol swab: **antiseptic**, **product** and **concentration** (*e.g* isopropyl alcohol 70%)			Y ( ) N ( ) P ( )		If 'Partially', indicate what is missing
116	**Product code** of the accessory	Y ( ) N ( )		Y ( ) N ( )		
117	For transfer device other than inverted cup and loop: **volume mark**	Y ( ) N ( ) NA ( )				
118	**Lot number**	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )	
119	For transfer device: indication of **'*in vitro* diagnostic' use**	Y ( ) N ( )				
120	**Expiration date**	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )		
121	If expiration date displayed: format **YYYY-MM**?	Y ( ) N ( ) NA ( )	Y ( ) N ( ) NA ( )	Y ( ) N ( ) NA ( )		
122	**Quantity indicated on** the outer package (symbol)	Y ( ) N ( ) NA ( )	Y ( ) N ( ) NA ( )	Y ( ) N ( ) NA ( )		
123	Specimen **volume transferred**	Y ( ) N ( )				
124	**Single use** (symbol)	Y ( ) N ( )	Y ( ) N ( )	Y ( ) N ( )		
[125]	*Is this accessory **sterile**? By what method?*		*Y ( ) N ( )* *Method:*	*Y ( ) N ( )* *Method:*		***TO BE COMPLETED BY MANUFACTURER***
[126]	*If applicable, **"sterile"** displayed?*		*Y ( ) N ( ) NA ( )*	*Y ( ) N ( ) NA ( )*		***TO BE COMPLETED AFTER MANUFACTURER'S FEEDBACK***
[127]	*If applicable, **sterilization method** displayed?*		*Y ( ) N ( ) NA ( )*	*Y ( ) N ( ) NA ( )*		***TO BE COMPLETED AFTER MANUFACTURER'S FEEDBACK***
128	**"Do not** use if package is **damaged"** (symbol)		Y ( ) N ( )	Y ( ) N ( )		
129	**"Do not swallow/eat**" and **"harmful"** (as text or symbols)			Y ( ) N ( ) P ( )	Y ( ) N ( ) P ( )	
[130]	*For warnings in text: **relevant language** is used?*			*Y ( ) N ( ) NA ( )*	*Y ( ) N ( ) NA ( )*	***TO BE COMPLETED BY MANUFACTURER***
131	If applicable, interpretation of **color change**				Y ( ) N ( ) NA ( )	

*The name of accessory can already include part of the intended use description

- Instructions for Use (IFU) –

		Reply	Comments	*Additional info:*
A.	**IFU text layout**:			
132	Does the **IFU layout** comply with the minimum standards for legibility (text size, spacing and font type)?	Y ( ) N ( )		*i.e.* Characters of at least 9 points // Interline spacing at least 3mm. Refer to **Box 2** in the Annex (AID) for a text example.
133	Is the IFU printed on a **paper** that is sufficiently thick to minimize **transparency**?	Y ( ) N ( )		
134	Is the IFU printed on **uncoated paper**? *i.e.* not glossy	Y ( ) N ( )		*Glossy paper reflects light and may hinder reading.*
135	**Important** information is **stressed** by using capitals, italics, underline, etc?	H ( ) M ( ) L ( )		
136	Is the text written in **short sentences** and using terms that are **easy to understand**?	H ( ) M ( ) L ( )		
137	Text is written as **one line per action**?	Y ( ) N ( )		
138	Are lists presented as **numbered** or **"bullet-point"** format?	Y ( ) N ( ) P ( )		
139	**Warnings** are clearly indicated?	Y ( ) N ( )		
[140]	*Have the procedure or IFU **changed substantially** since the last version of the product?*	Y ( ) N ( )		***TO BE COMPLETED BY MANUFACTURER***
[141]	*If the procedure or IFU has changed, is there an **additional warning** about this in the IFU?*	*Y ( ) N ( ) NA ( )*	*CDC may comment if applicable:*	***TO BE COMPLETED AFTER MANUFACTURER'S FEEDBACK***
[142]	*If an additional warning is displayed, does it include information about the **changes** (e.g. differences are highlighted for example shaded in grey) and **effective date**?*	*Y ( ) N ( ) NA ( )*	*CDC may comment if applicable:*	***TO BE COMPLETED AFTER MANUFACTURER'S FEEDBACK***
B.	**IFU figures layout**:			
143	Is the **resolution of figures** clear enough to identify all items represented?	H ( ) M ( ) L ( ) NA ( )		H: All figures are clearly visible M: Some are not clear L: Most/all with low resolution
144	Do all figures consist of **drawings** (instead of photographs)?	Y ( ) N ( ) NA ( )		
145	Figures are always at the **left side** (with text at the right side)?	Y ( ) N ( ) P ( ) NA ( )		
146	Are all figures **referred** in the IFU text?	Y ( ) N ( ) NA ( )		
147	Do all figures **match the real-life** situation (*e.g.* device, transfer device, gloves, right-handed operator…)?*	H ( ) M ( ) L ( ) NA ( )		H: All figures match M: Some figures do not match L: Most/all figures do not match
C.	**Product information**:			
148	**Product name**	Y ( ) N ( ) P ( )		
149	**Product code**	Y ( ) N ( )		
150	**Number of tests** provided in the kit	Y ( ) N ( )		

* See as example the *Generic Job-aids for Malaria RDTs* (WHO-FIND): www.finddiagnostics.org/programs/malaria-afs/malaria/completed-projects/training-materials/rdt-job-aids/generic/pan-pf-rdt-training.html

		Reply	Comments	*Additional info:*
D.	**Intended use**:			
151	**Function** of the product (*e.g.* detect *Plasmodium*, differentiate *spp*., etc.)	Y ( ) N ( )		
152	What is **detected** by the assay (*e.g.* which antigens, etc.)	Y ( ) N ( )		
153	**Clinical** indication (*e.g.* diagnostic, not monitoring)	Y ( ) N ( )		
154	Indication that the product is **qualitative** (not quantitative)	Y ( ) N ( )		
155	General description of the **principle of the assay** (*i.e*. apply sample+buffer, migration, antibody binding, colored lines, etc.)	Y ( ) N ( ) P ( )		See example – **Box 3** in the Annex (AID)
156	Description of the main **components** and **ingredients** (*e.g.* type of antibodies, buffer composition, etc.)	Y ( ) N ( ) P ( )		
157	Indication of the **intended user** (*i.e.* trained user)	Y ( ) N ( )		
158	**Type of specimen** required (*e.g.* capillary blood, venous blood with anticoagulant, etc.)	Y ( ) N ( )		
159	**Time** between specimen **collection** and specimen **testing**	Y ( ) N ( )		
E.	**Warnings and precautions**: *(can be included as a list OR along the IFU text)*			
160	For ***in vitro*** diagnostic use **only**	Y ( ) N ( )		
161	**Read the instructions** carefully before performing the test	Y ( ) N ( )		
162	Apply standard **biosafety precautions** for handling and disposal of potentially infective material	Y ( ) N ( ) P ( )		*e.g.* handle all specimens as potentially infectious, wear gloves, avoid splashing and aerosol formation, clean up spills using appropriate disinfectant…
163	Buffer contains XX% **sodium azide** as a preservative which may be toxic if ingested (when disposed of through a sink, flush with large quantities of water).	Y ( ) N ( ) NA ( )		
164	Do **not** use any **other buffer** than the buffer supplied within this kit	Y ( ) N ( )		
165	Do **not** use any **other specimen** than whole blood	Y ( ) N ( ) NA ( )		
166	Do **not** use the RDT kit beyond the **expiration date**	Y ( ) N ( )		
167	Do **not** use if the packaging is **damaged**	Y ( ) N ( )		
168	Do **not** use if the product has been exposed to excessive **heat or humidity**	Y ( ) N ( )		
169	Perform the test immediately **after opening** of the cassette packaging	Y ( ) N ( )		
170	Do **not re-use** the test	Y ( ) N ( )		

		Reply	Comments
F.	**Materials**:		
●	Materials provided:		
171	**Cassette** (and quantity) or **cassette package** [each containing: 1 **test device**, 1 **desiccant**, etc.] (and quantity)	Y ( ) N ( ) P ( )	
172	**Buffer** bottle/s (XX ml or number of testings) and quantity	Y ( ) N ( ) P ( )	
173	**Specimen transfer devices** (type; X µl) and quantity	Y ( ) N ( ) P ( ) NA ( )	
174	Single-use **lancets** (type) and quantity	Y ( ) N ( ) P ( ) NA ( )	
175	**Alcohol swabs** and quantity	Y ( ) N ( ) P ( ) NA ( )	
176	**1 Instructions for use**	Y ( ) N ( ) P ( )	
177	Are all kit components **referred to** and **represented** in the same manner in the IFU/labeling?	Y ( ) N ( ) P ( )	
●	Materials required but not provided:		
178	**New pair of disposable gloves**	Y ( ) N ( ) P ( )	
179	**Timer**	Y ( ) N ( )	
180	**Biosafety sharps** container	Y ( ) N ( )	
181	**Biohazard waste** container	Y ( ) N ( )	
182	**Pen**	Y ( ) N ( )	
183	If whole blood is collected by venipuncture, **venipuncture** blood collection materials and precision pipette, plus tips	Y ( ) N ( ) P ( )	
184	**Extra** lancets and alcohol swabs, if needed (*e.g.* lancet misfires, lancet does not produce sufficient blood volume, alcohol swab is dried out, etc.)	Y ( ) N ( ) P ( ) NA ( )	
185	**Other** (specify in *Comments*)	Y ( ) N ( )	
G.	**Storage and stability**:		
186	Store the kit between **X-XX °C**.	Y ( ) N ( )	
187	Do **not** store the kit in the **freezer.**	Y ( ) N ( )	
188	Protect the kit from **humidity**.	Y ( ) N ( )	
189	The kit is stable until the **expiration date** indicated on the box when stored as specified.	Y ( ) N ( ) P ( )	
190	The buffer is stable for **XX** months (or until the expiry date) even after opening.	Y ( ) N ( ) P ( )	
H.	**Procedure**:		
►	Before testing:		
191	Prepare all **materials** (provided and not provided in the kit)	Y ( ) N ( )	
192	If stored in **refrigerator**, bring to room temperature at least **30 min before** use	Y ( ) N ( )	
193	Confirm the kit is in good conditions (*i.e.* check **expiration date**, **packaging** not damaged, **desiccant**)	Y ( ) N ( ) P ( )	
194	Place cassette on **horizontal surface**	Y ( ) N ( )	
195	Write **patient identification** on the cassette	Y ( ) N ( )	
196	Put on new **gloves**	Y ( ) N ( )	
197	If needed, additional instructions to **open buffer** bottle	Y ( ) N ( ) NA ( )	

		Reply	Comments
►	Test procedure:		
→	*Capillary whole blood from finger prick*		
198	Prepare the finger and use of the **alcohol swab**	Y ( ) N ( ) P*( )	
199	Use of the **lancet**	Y ( ) N ( ) P*( )	
200	Use of the **specimen transfer device** (blood collection and transfer to sample well)	Y ( ) N ( ) P*( )	
201	Application of the **buffer**	Y ( ) N ( ) P*( )	
202	Set countdown **reading time**	Y ( ) N ( )	
203	**Disposal** of used materials in the biosafety **sharps** container: lancet	Y ( ) N ( )	
204	**Disposal** of used materials in the biohazard **waste** container: alcohol swab, transfer device and gloves	Y ( ) N ( ) P ( )	
→	*Venous whole blood from venipuncture*		
205	Collection by standard **venipuncture**	Y ( ) N ( )	
206	Transfer X µl with a precision **pipette**	Y ( ) N ( )	
►	Interpretation of the test result:		
207	Read the results **after XX min**, but **no later** than **XX min**	Y ( ) N ( )	
	Description of different **result possibilities** [see example in ***Table 1*** *– Annex (AID)]:*		
208	All line combinations for NEGATIVE result are described and depicted	Y ( ) N ( )	
209	All line combinations for POSITIVE result are described and depicted	Y ( ) N ( )	
210	If applicable, interpretation of different POSITIVE results is clearly and correctly described, with clarification of the species	Y ( ) N ( ) NA ( )	
211	All line combinations for INVALID result are described and depicted	Y ( ) N ( )	
212	Following action for INVALID result (*i.e.* repeat the test) is clearly stated	Y ( ) N ( )	
213	Consider a **faint test line** as a positive result	Y ( ) N ( )	
214	Where possible, have the results confirmed by a **second reader**	Y ( ) N ( )	
215	**Record** the test results	Y ( ) N ( )	
216	Consult the **national guidelines** for malaria case management	Y ( ) N ( )	
217	The test does **not differentiate** between *P. vivax, P. ovale and P. malariae*	Y ( ) N ( ) NA ( )	

** P (partially described): if the procedure is mentioned but not fully described*

		Reply	Comments
I.	**Limitations**:		
■	False negatives:		
218	**Definition** of false negative result (no test line, but patient has malaria)	Y ( ) N ( )	
→	**Causes** of false negative result, including:		
219	a) very low antigen concentrations/parasite densities (*e.g.* < 100 p/µl; most clinical cases are higher)	Y ( ) N ( )	
220	b) very high parasite densities (very exceptional, prozone or high-hook effect) for the HRP2 antigen	Y ( ) N ( ) NA ( )	
221	c) deletions in the HRP2 gene resulting in no production of the antigen (only significantly present in the Peruvian Amazon)	Y ( ) N ( ) NA ( )	
222	d) high fraction of interstitial fluid due to “milking” of fingertip	Y ( ) N ( )	
■	False positives:		
223	**Definition** of false positive result (test line visible, but patient does not have malaria)	Y ( ) N ( )	
→	**Causes** of false positive result, including:		
224	a) rheumatoid factors, antinuclear antibodies	Y ( ) N ( )	
225	b) viral infection (such as hepatitis B or hepatitis C, dengue)	Y ( ) N ( )	
226	c) parasitic infection (such as schistosomiasis and trypanosomiasis)	Y ( ) N ( )	
■	Invalid results:		
227	Definition of **invalid result** (no control line OR incomplete clearing background)	Y ( ) N ( )	
228	**Cause** of invalid result: lipaemic and icteric specimens	Y ( ) N ( )	
■	Notes:		
229	The presence of the **control line** only means that migration of the test occurred. It does **not** guarantee that the test and specimen were correctly stored and used.	Y ( ) N ( )	
230	Sensitivity for detecting malaria is lower in the case of ***P. ovale*** and ***P. malariae***	Y ( ) N ( ) NA ( )	

		Reply	Comments	*Additional info:*
J.	**Performance specifications**:			
231	**Analytical sensitivity** (detection limit)	Y ( ) N ( )		
232	**Analytical specificity** (rheumatoid factor, antinuclear antibody, other infections and influence of lipemic/icteric/hemolyzed specimens)	Y ( ) N ( ) P ( )		
233	**Diagnostic sensitivity**	Y ( ) N ( )		
234	**Diagnostic specificity**	Y ( ) N ( )		
235	**Repeatability** (test-related, laboratory conditions)	Y ( ) N ( )		
236	**Reproducibility** (operator-related, field conditions)	Y ( ) N ( )		
237	**Numbers of specimens** used (and if applicable, confidence intervals)	Y ( ) N ( )		
238	**Type of study** and setting, geographic place, study period and population	Y ( ) N ( ) P ( )		*e.g.* laboratory study on stored specimens, clinical study, field study…
239	**Parasite densities** and **reference methods** when appropriate	Y ( ) N ( )		*e.g.* in case of diagnostic sensitivity
240	**Bibliography / reference** list is included?	Y ( ) N ( )		
241	Results are presented in a **clear way** (*e.g.* table)?	H ( ) M ( ) L ( )		
242	**Different specifications** for the 4 *Plasmodium* species are provided?	Y ( ) N ( ) NA ( )		
K.	**Bibliography**:			
243	Product-related publications, including test kit evaluations (product studies)	Y ( ) N ( )		
	General publications, including:			
244	a) Biosafety and Sampling	Y ( ) N ( )		
245	b) WHO Product Testing rounds	Y ( ) N ( ) NA ( )		
246	c) RDT implementation problems, end-user errors (prozone, buffer substitution, false positive, etc.)	Y ( ) N ( )		
L.	**Contact of Manufacturer**:			
247	**Name** of the legal manufacturer	Y ( ) N ( )		
248	**Physical address** of the manufacturing site	Y ( ) N ( )		
249	Contact for **technical assistance** (telephone/fax number, email address)	Y ( ) N ( ) P ( )		
M.	**IFU version details**:			
250	IFU **version number**	Y ( ) N ( )		
251	IFU **language**	Y ( ) N ( )		
252	IFU **date of issue**	Y ( ) N ( )		
N.	**Symbol key**:			
253	**Symbol key** included?	Y ( ) N ( ) P ( )		

Y=yes; N=no; NA=not applicable; P=partially; H=high; M=medium; L=low