

Pregnancy Tests for Family Planning

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receive the contraceptive method. Another obstacle to use of IUCDs and injectable and implantable contraceptives is delaying the start until the menstrual period begins—even sometimes limited to a specific day. In truth, these methods can be started any time if non-pregnancy is established.

-“Medical Barriers to Access to Family Planning”
Shelton, Angle and Jacobstein, Lancet, 1992

It appeared that some providers gave methods only to women who were menstruating. Seven of 35 current or past contraceptive users in the qualitative sample reported either being asked to show proof of menstruation or being told to return during their next period. While 6 women indicated receiving a method on their first visit, at least 7 others reported having to return, sometimes multiple times, mostly because they were not menstruating during the clinic visit or to obtain pregnancy test results. A large proportion (43%) of survey respondents agreed with the statement that the nurse would ask to see their menstrual pad if they went for family planning.

-“Getting to 70%: Barriers to modern contraceptive use for women in Rwanda”
Brunie, Tolley, Ngabo, Wesson, Chen, 2013

Menstrual Status as a Barrier to Access – Then and Now

“

When you get there, they ask if you are having your period. When it is ‘no,’ they give you another appointment. When it is ‘yes,’ they give you cotton wool and you go somewhere discreet to put some blood [on it] and come back to show it to the provider. It is only then that the provider shows you the methods.

49-YEAR-OLD DMPA
USER, RWANDA

”

- **Lack of menstruation a barrier to contraceptive service delivery** – providers use menses to rule out pregnancy; clients turned away for same-day FP services
- **Many new family planning clients are not menstruating when they visit the clinic**
- **Few non-menstruating clients are actually pregnant**
- **According to WHO, no known harm occurs to either a pregnant woman or a fetus from exposure to hormonal family planning methods***

*In case of the IUD, it is important to rule out pregnancy because inserting an IUD in a woman who is already pregnant may result in septic miscarriage, which is a serious complication.

What does the evidence tell us?



As of 2006...

- The Pregnancy Checklist was adopted in at least 15 countries and available in five language (English, Spanish, French, Romanian, and Kiswahili)
- Included in the Global Handbook for Family Planning and the WHO Decision-Making Tool

However...

- There are instances when the checklist cannot exclude pregnancy
- Some providers don't like/ trust the checklist

The Pregnancy Checklist— Then and Now

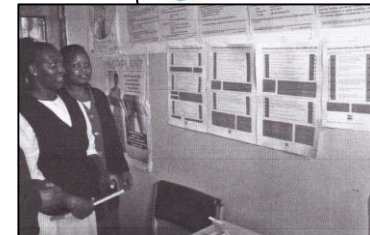
How to be Reasonably Sure a Client is Not Pregnant
Ask the client questions 1-6. As soon as the client answers YES to any question, stop, and follow the instructions.

NO	1. Did you have a baby less than 6 months ago, are you fully or nearly fully breastfeeding, and have you had no menstrual period since then?	YES
NO	2. Have you abstained from sexual intercourse since your last menstrual period or delivery?	YES
NO	3. Have you had a baby in the last 4 weeks?	YES
NO	4. Did your last menstrual period start within the past 7 days (or within the past 12 days if you are planning to use an IUD)?	YES
NO	5. Have you had a miscarriage or abortion in the past 7 days (or within the past 12 days if you are planning to use an IUD)?	YES
NO	6. Have you been using a reliable contraceptive method consistently and correctly?	YES

If the client answered NO to all of the questions, pregnancy cannot be ruled out. The client should avoid medicines or use a pregnancy test.

If the client answered YES to at least one of the questions and she is free of signs or symptoms of pregnancy, provide client with desired method.

USAID fhi Family Health International © 2008



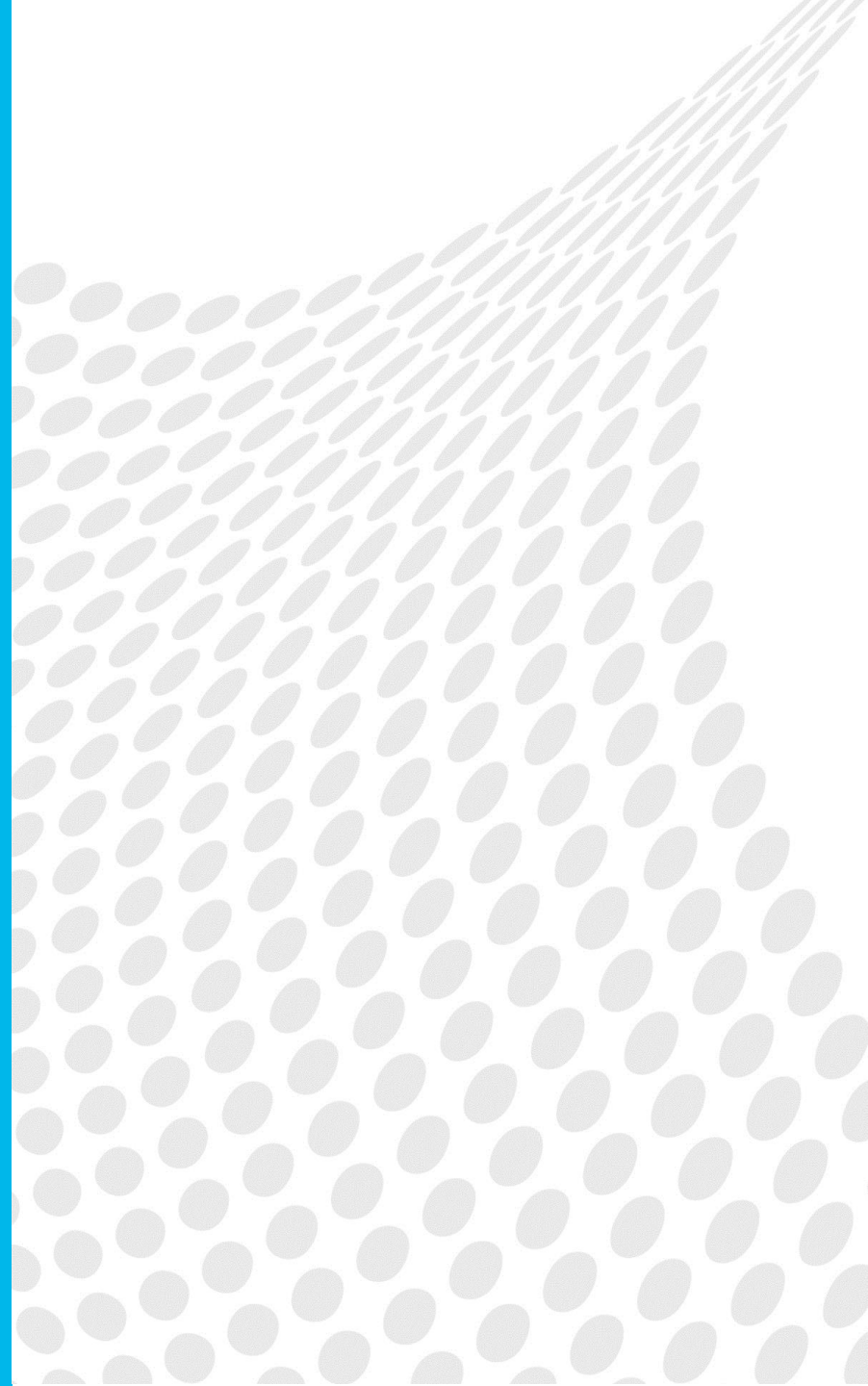
Pregnancy tests complement Pregnancy Checklist

Pregnancy tests available
for purchase for \leq US\$0.10



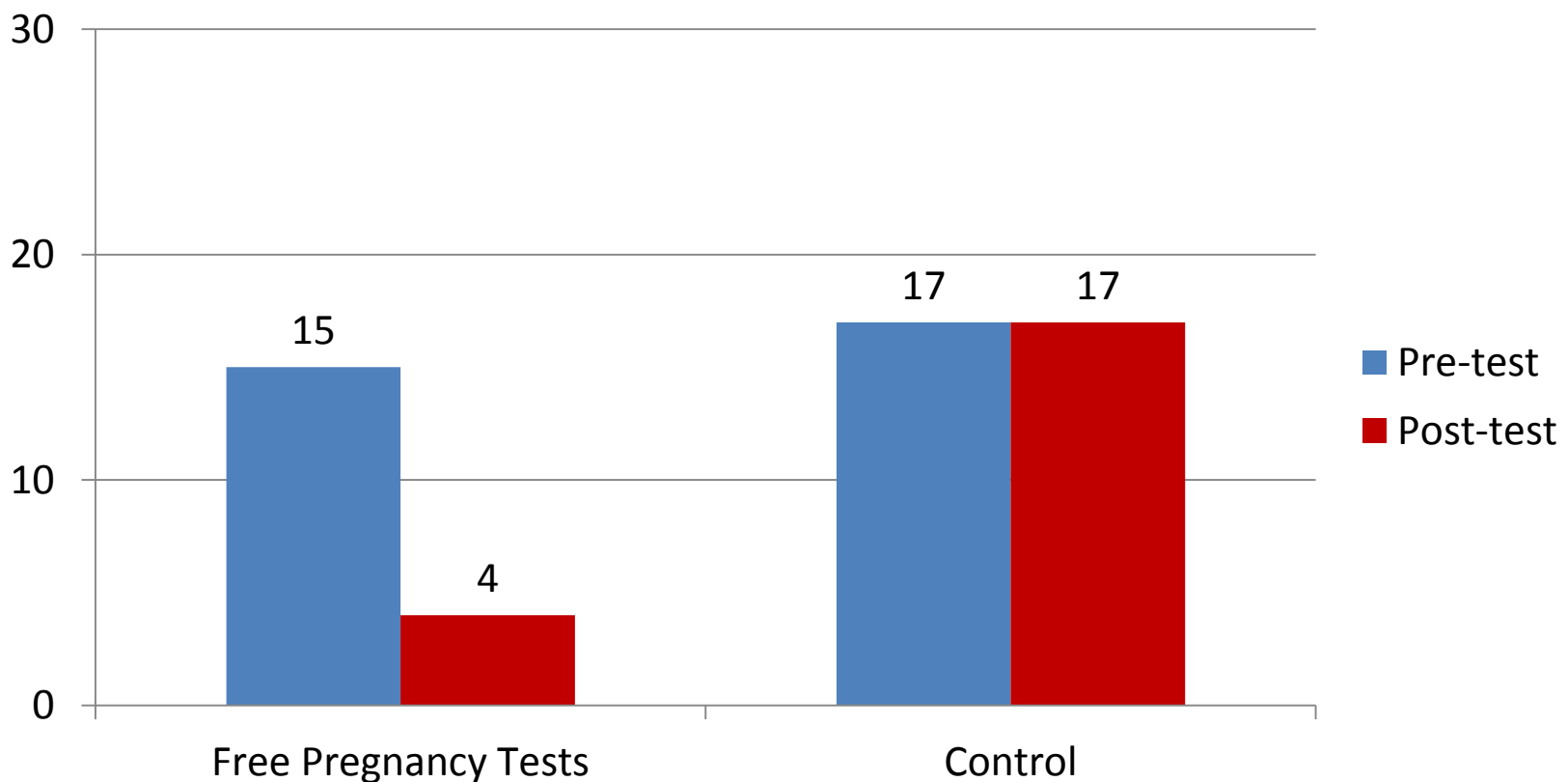
Additional benefits:

- FP demand generation
- Social marketing
- Tool for improving continuation of progestin-only methods
- Contribute to decrease in gestational age for clients seeking ANC and abortion services



Pregnancy Tests: Research in Zambia (FHI 360)

% New, Non-Menstruating Clients Denied Effective Method

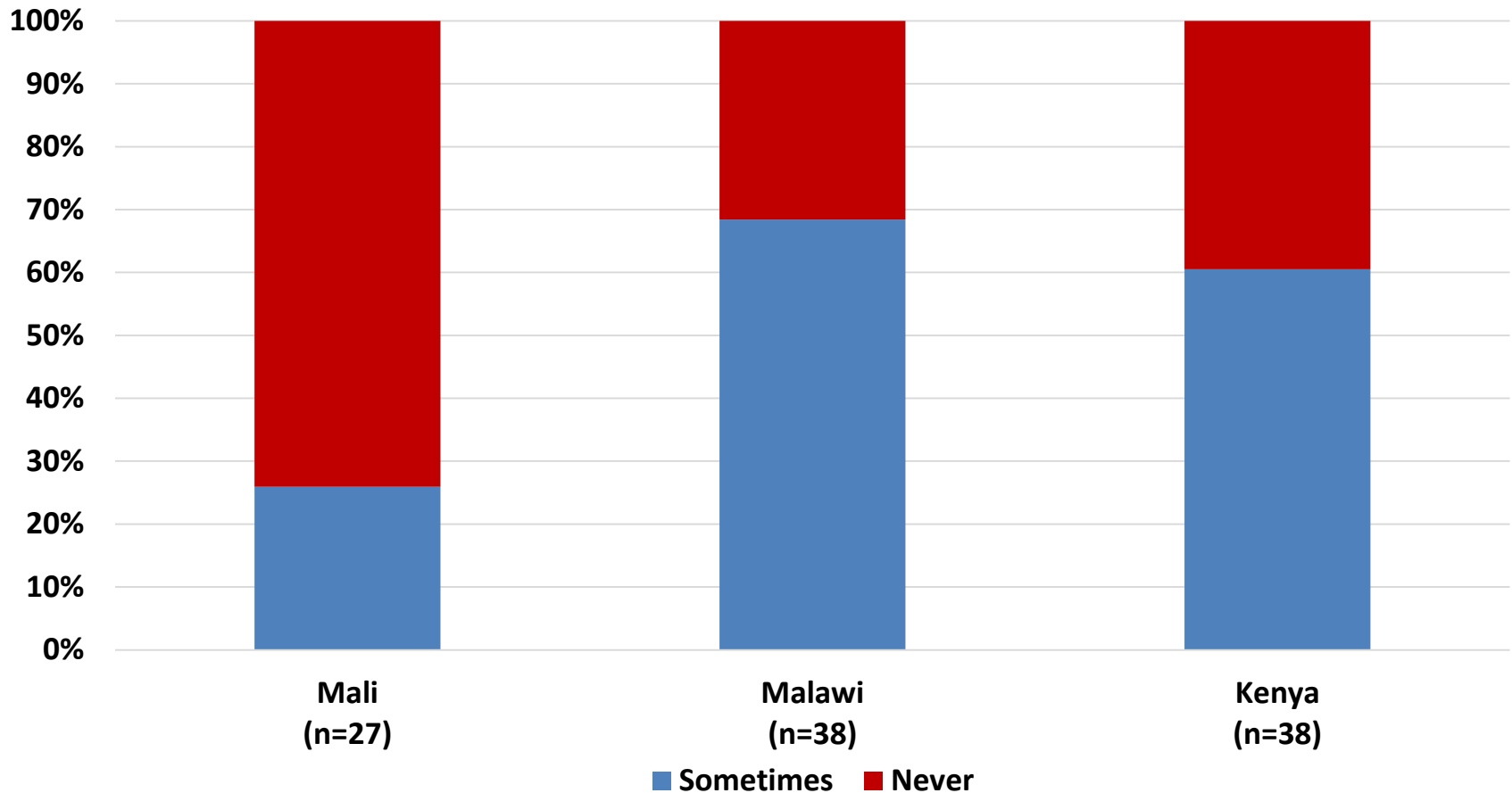


2015 Innovation Fund project: Price of ‘least expensive’ pregnancy test available in US dollars by facility type

		Mali (n=30)	Malawi (n=39)	Kenya (n=42)
Private	mean* [range], US\$	1.99 [0.41-3.28]	0.95 [0.35-1.77]	1.94 [0.98-5.87]
	sample size	n=14	n=19	n=20
	<i>No charge for test</i>	(n=1)	(n=2)	(n=5)
Public	mean* [range], US\$	1.72 [0.82-2.46]	0.35 [0.35-0.35]	1.86 [0.98-4.89]
	sample size	n=10	n=9	n=15
	<i>no charge for test</i>	(n=1)	(n=8)	(n=10)
Pharmacy / Drug shop	mean* [range], US\$	2.12 [1.15-2.46]	0.66 [0.35-0.88]	0.84 [0.49-1.96]
	sample size	n=6	n=11	n=7
	<i>no charge for test</i>	(n=0)	(n=0)	(n=0)

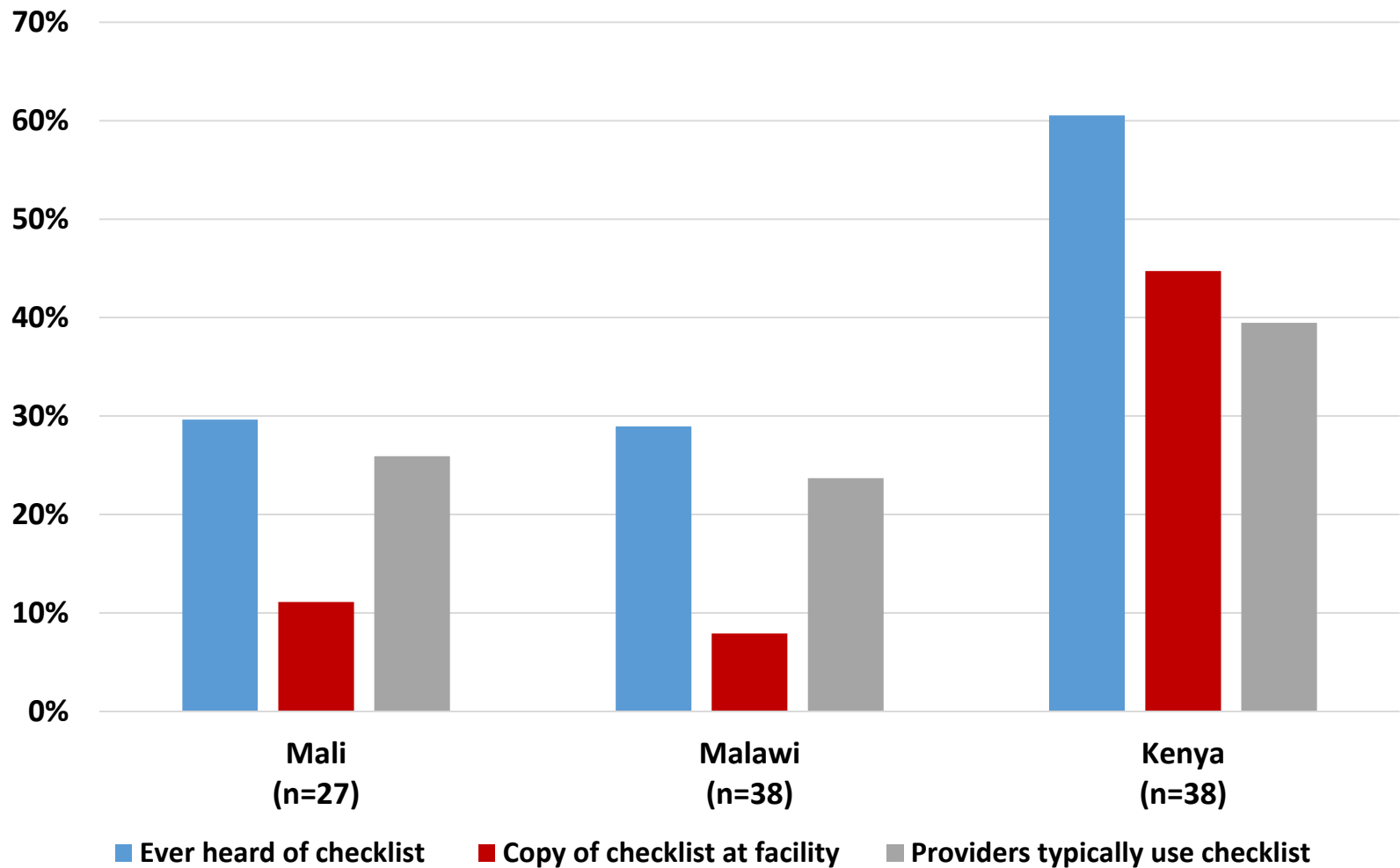
*Mean calculated among facilities that reported charging for the test. Reflects the “least expensive” pregnancy test available at each facility

Innovation Fund Project: Are Women Ever Sent Away to Buy Tests? (Public & private facilities only)



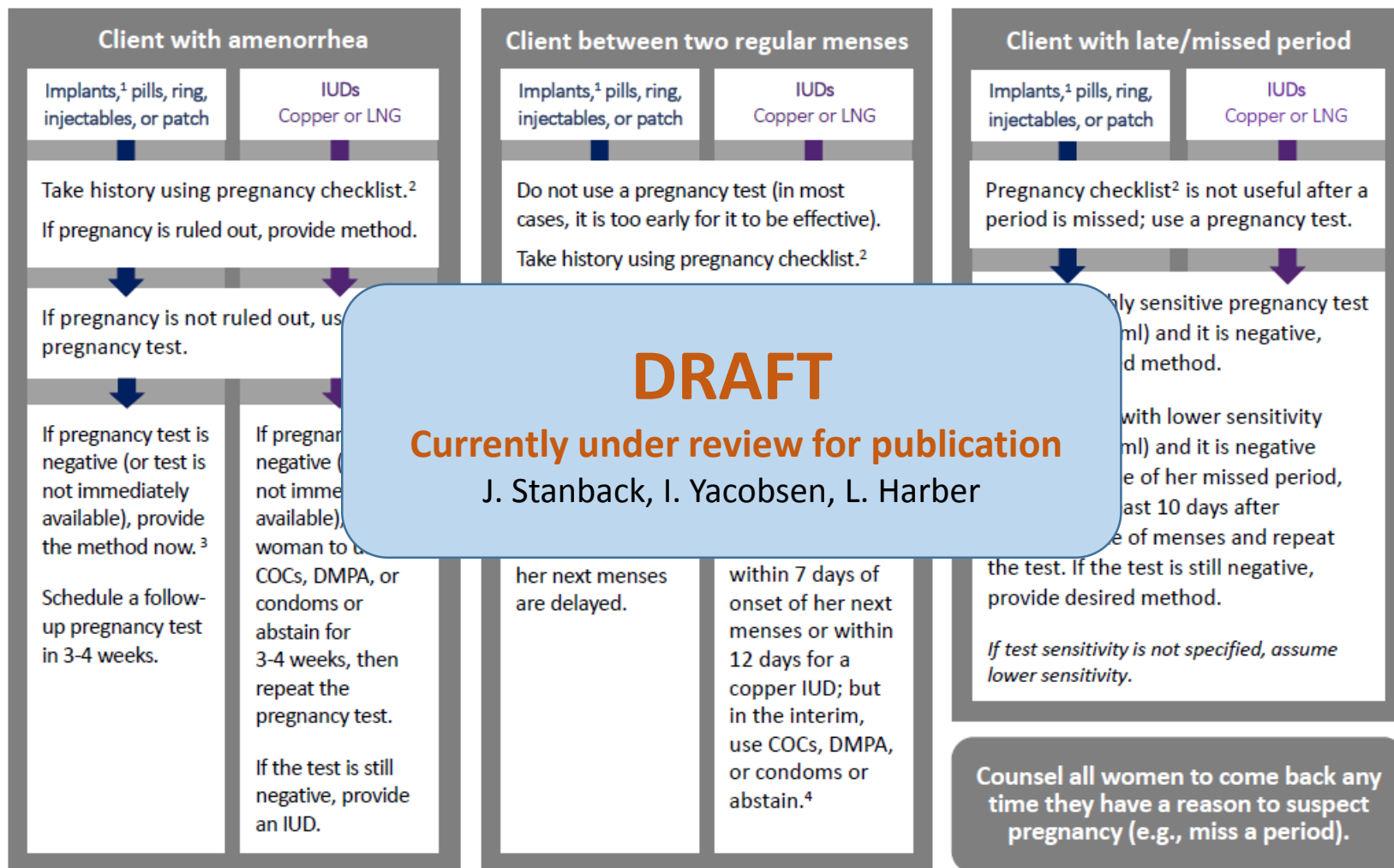
Results from following question: "If there are either occasional stock-outs of pregnancy tests or if pregnancy tests are never available at this facility, are women ever instructed to purchase pregnancy tests elsewhere?"

Innovation Fund Project: Awareness, availability and use of Pregnancy Checklist (public & private facilities)

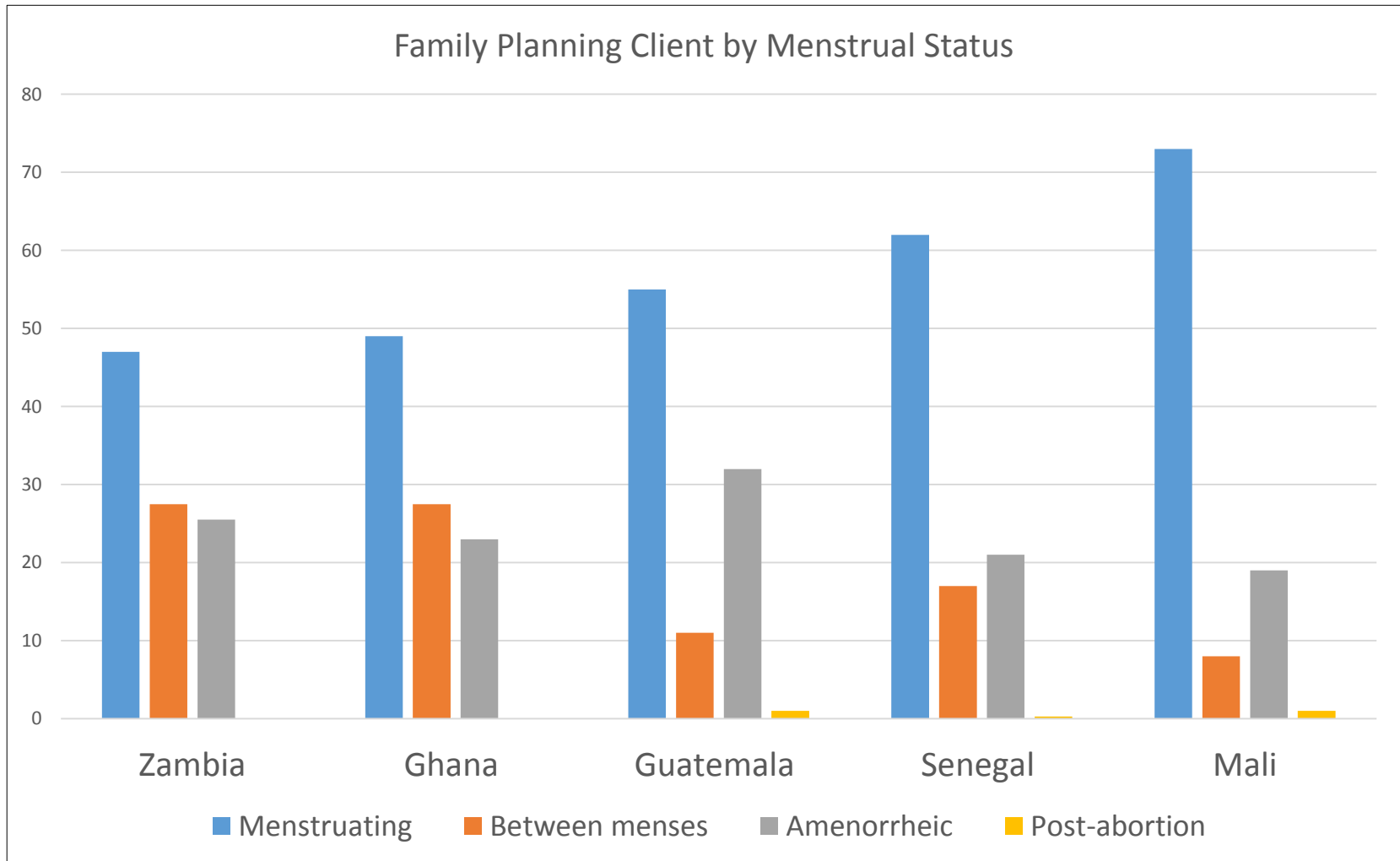


New Clinical Job Aid for Providers – When to Use Checklist versus Pregnancy Tests

Figure 2. Job Aid for Ruling Out Pregnancy Prior to Contraceptive Initiation



FP Clients by Menstrual Status



- **International procurement is split across a number of buyers – relatively ‘low volume and low value,’** which often translates into no dedicated resourcing for quality assurance, limited sharing of information and pooling of resources
- **Through the 2015 RHSC Innovation Fund project, stakeholders highlighted a number of concerns related to quality:**
 - concerns about fake, counterfeit and questionable CE-marked products entering markets
 - uncertainty and confusion around quality assurance standards
 - limited regulatory approval/oversight
 - limited visibility for procurers on the supply side

New Guidance Document for Procurement of Pregnancy Tests

“

We cannot give you the data of how many [inaccurate results]. There is quite a bit that goes on. This is really an area of concern for us

”

*Interview with Kenya
Medical Laboratory
Technicians and
Technologist Board
(KMLTTB) official, Kenya*

Guidance Document For Procurement of Pregnancy Tests: Scope of Project

FHI 360 with USAID funding through the *Envision FP* project, and in consultation with RHSC MDAWG workstream and expert procurement committee, are developing a guidance document for procurers of pregnancy tests.

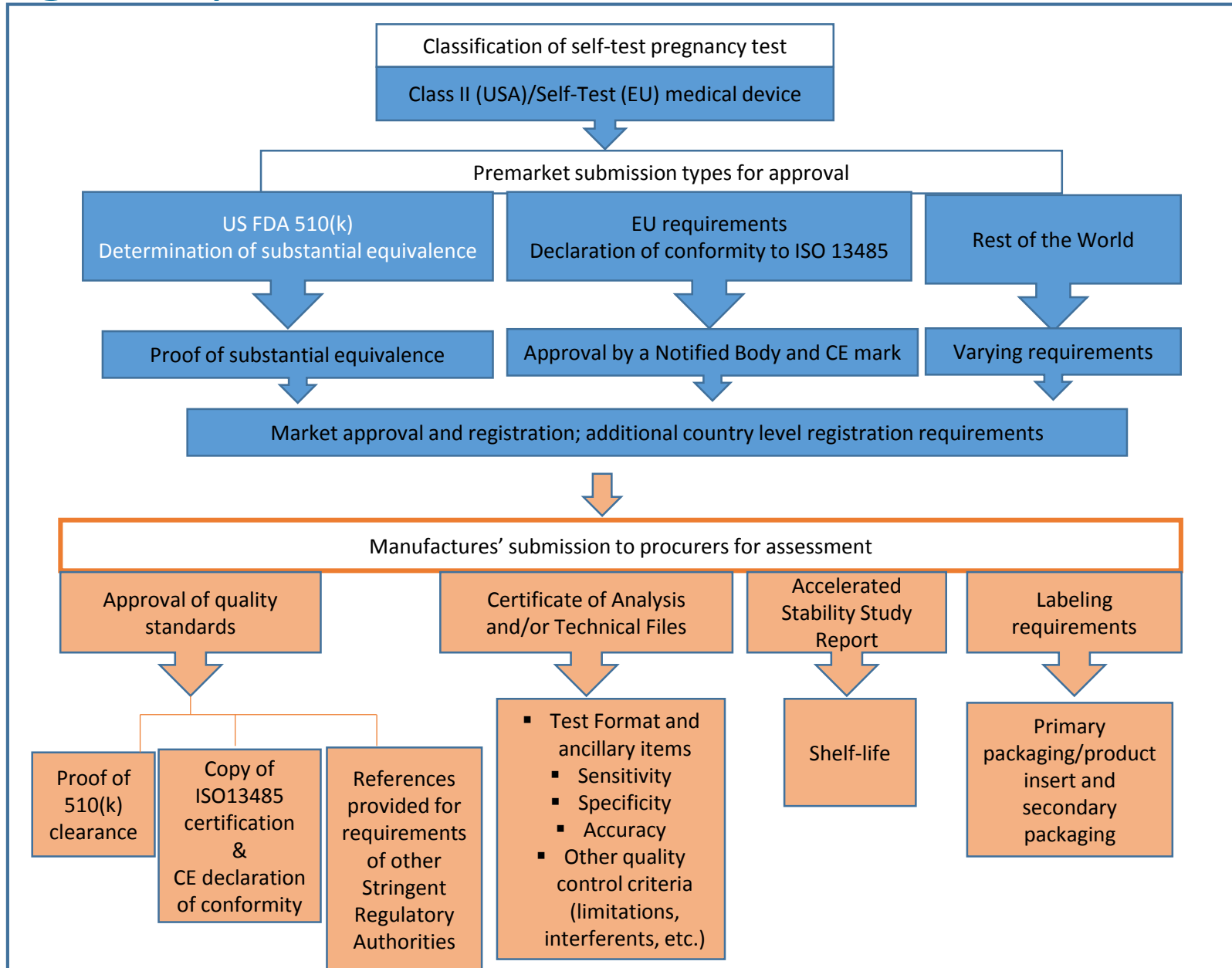
■ Goals:

- Factor in best practices from a number of key documents describing global standards and performance criteria for rapid in vitro diagnostics.
- Broadly outline requirements for quality standards and provide details on technical specifications to optimize the selection of high quality pregnancy tests

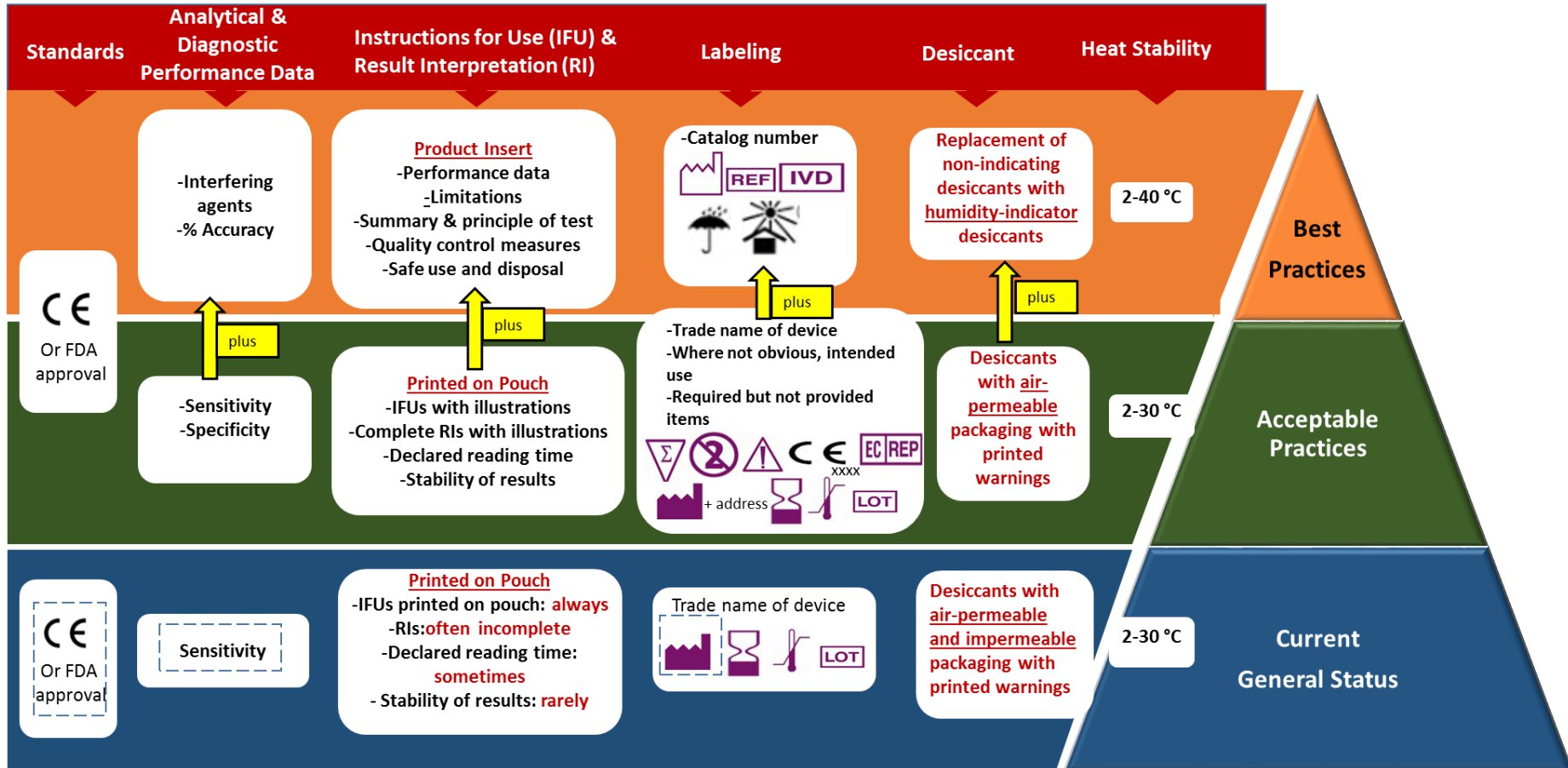
■ Intended audience:

- Individuals responsible for the procurement, supply, and quality assurance of pregnancy test kits at a global, national and/or local level including procurement officers, health officers and supply chain managers responsible for selecting, procuring or assisting in the procurement of pregnancy tests for use in the public and private sectors.

Pregnancy Tests: Areas of Guidance Covered



Pregnancy Tests - Best Practice, Acceptable Practice & Current General Status



 Low prevalence

Pregnancy Tests – Checklist and Tools for Procurers

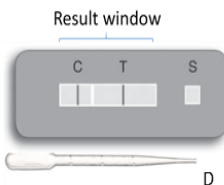
15 Annexes

15.1 Annex S1: Checklist for procurers

Procurers may use this checklist to verify manufacturer's compliance with acceptable standards as part of the product selection process. Items shaded in green are those listed under 'best practices', and therefore, are recommended to adopt as the country regulatory infrastructure improves or at procurer's discretion based on organizational risk analysis.

Commercial name of pregnancy test				
Manufacturer				
Lot number				
Date of assessment				
Name of assessor				
	Yes	No	NA	Comments/problems
List of Documents to be Provided by Manufacturer				
ISO 13485 Certification				
CE Declaration of Conformity (if applicable)				
FDA 510 Clearance (if applicable)				
Product Stability Documentation				
Certificate of Analysis				
Technical File				
Test results from independent Quality Control Tests (if applicable)				
Quality Standards				
Manufacturer compliant with ISO 13485				
Compliant with a different standard (state the standard under comments)				
Product is CE marked				
CE mark is accompanied by the identification number of the notified body				
Product is US FDA regulated				
Product is regulated by another party (state the party in the comments column)				
Labeling/Marking on Secondary Packaging (Carton and Boxes)				
Commercial name of the test included				
Batch/lot number included				

A. Example of cassette with a well for urine sample



Cassette-type

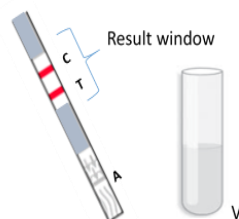
The strip is encased in a plastic cassette. Key features are: control line (C), test line (T) and a sample-well indicating where urine sample is to be added (S)

Ancillary item

Dropper (D), clean cup/tube

How test is to be used: Collect urine in a clean cup/tube → Using the dropper, transfer a specified volume of urine into the sample-well, placed on a flat surface with result window facing up → Read results after the specified period of time

B. Example of dipstick



Dipstick

The strip is mounted on a laminated strip. Key features are: control line (C), test line (T), and absorbent pad to wick the urine (A)

Ancillary item

a clean cup/tube for urine collection (V)

How test is to be used: Collect urine in a clean cup/tube → Dip the dipstick in urine up to the line indicated by arrows (A) for the specified period of time → Place the dipstick flat on a surface, with the result window facing up, for the specified period of time for results to develop

Includes a number of useful tools for procurers

Pregnancy Tests - QA Work Instructions

- Goal - to develop work instructions for QA of specificity, sensitivity, accuracy, and package seal integrity
- Intended audience: any laboratory interested in evaluating pregnancy tests (i.e., Africa, Asia, and South America)
- Information obtained from publically available sources, and not from proprietary sources (i.e., manufacturers / suppliers)
- Sampling plans / criteria for different scenarios:
 - product qualification
 - pre-shipment testing
 - post-shipment testing
 - stability study evaluations

Pregnancy Tests - QA Work Instructions

Overall Sampling Plans and Specifications for Different Testing Scenarios				
Assumed Lot size (35,000 – 150,000)	Product Qualification	Large Scale	Pre / Post / Stability Time Point	Small Scale
Category 1 (Performance)	120 total units	Sensitivity – ≥ 95% positive	28 units at high conc.	Sensitivity – ≥ 95% positive
			Specificity – Accept ≤ 3 failures	
Positive Controls (hCG x 6)				
Negative Controls (Blank + interferences)	80 total units	Accuracy – % of true pos./neg. per number tested	16 Blank & 16 Glucose	Accuracy – % of true pos./neg. per number tested
Category 2 – Package Integrity	32 units	Accept ≤ 2 failures	13 units	Accept ≤ 1 failure