

A self-collection device for cervical cytology: iPap™

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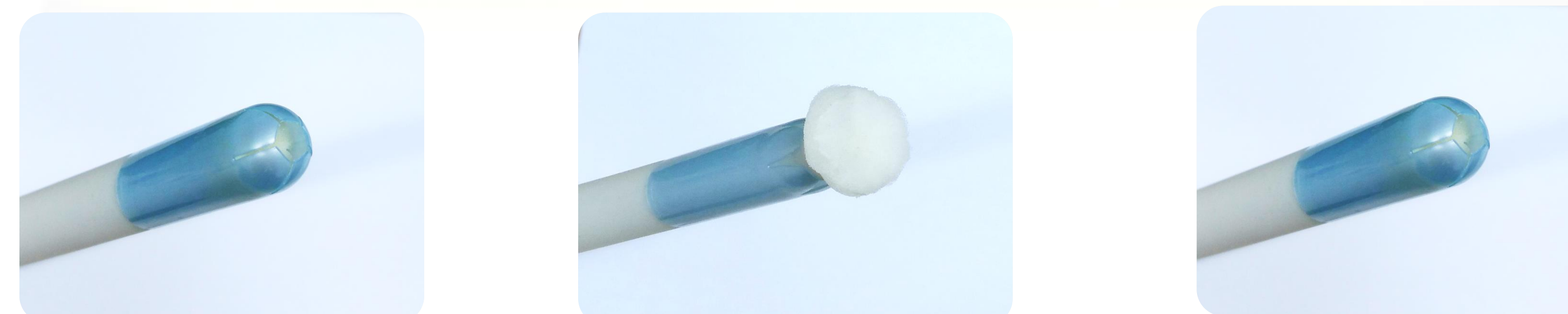
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Objective: To facilitate wider dissemination of cervical cancer screening, especially in developing countries, we assessed the suitability of the iPap™ Personal Specimen Collector to obtain a sufficient quantity of cervical cells for standard liquid-based cytology.

Methods: A novel self-collection device (iPap) has been developed that allows women to collect cervical cells without the need for a visit to a clinician. iPap was designed to collect cells from the cervix while minimizing cell collection from the vaginal wall. This personal specimen collector and associated Instructions for Use were provided to 22 women for evaluation, and the resulting specimens were evaluated using standard cytological methodologies.



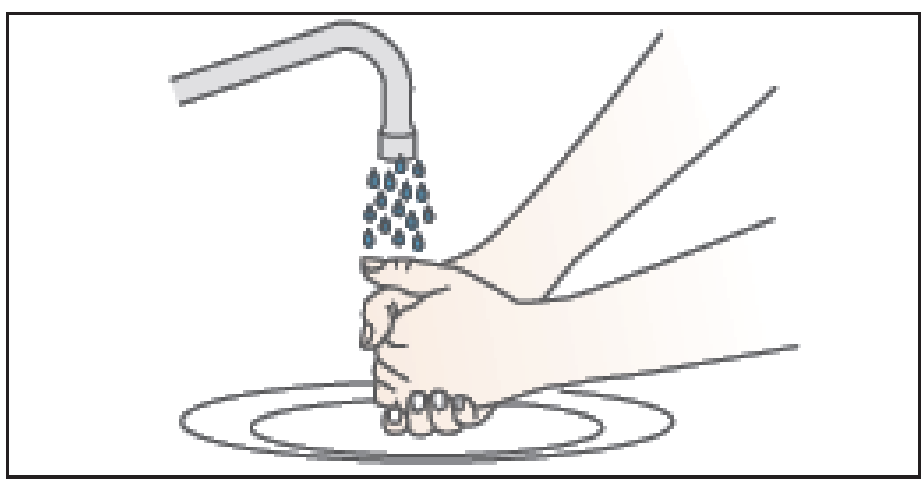
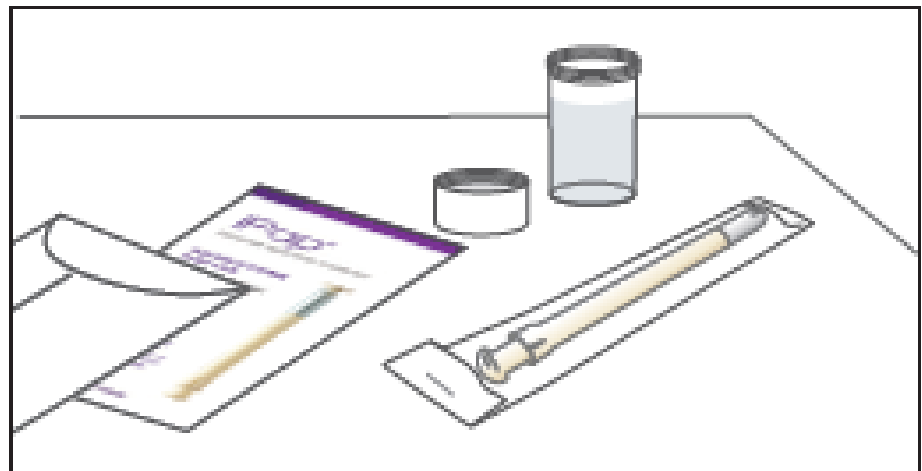
Novel self-collector designed to target collection of cervical cells



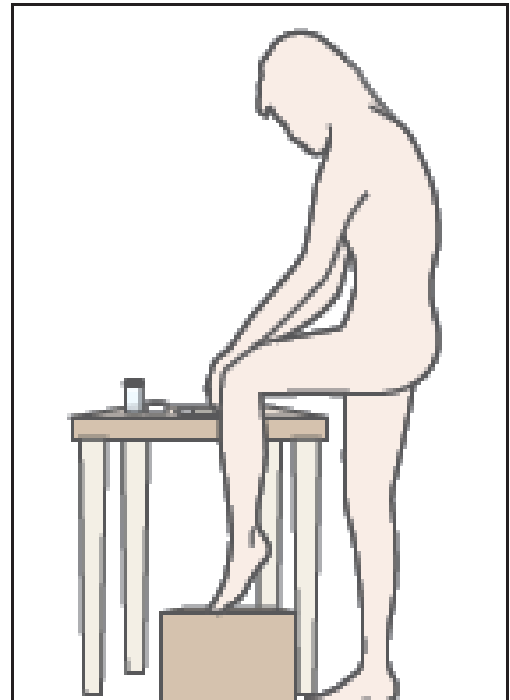
1. Protective covering minimizes the collector sponge tips from contacting vaginal cells upon entry into vaginal canal
2. Collector sponge tip is deployed when the tip is in contact with cervix and the cells are collected on the tip
3. When removing, sponge tip retracts and the protective covering minimizes the tips from contacting vaginal cells

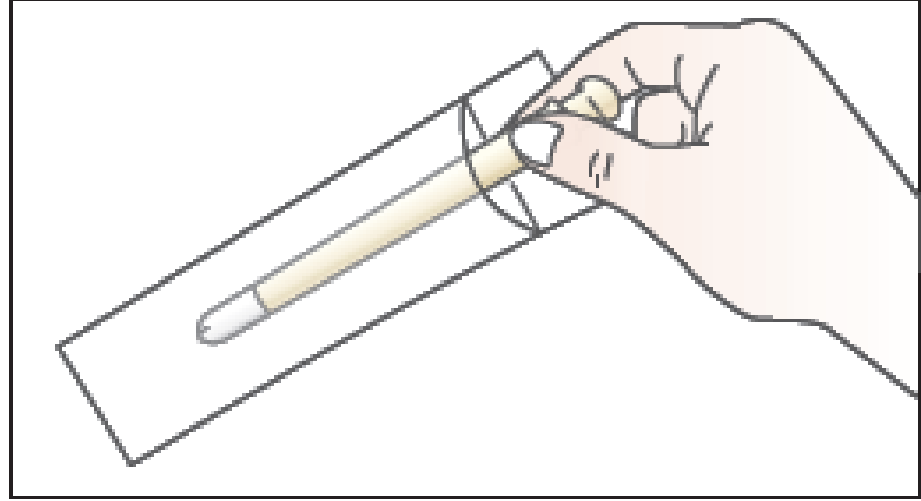
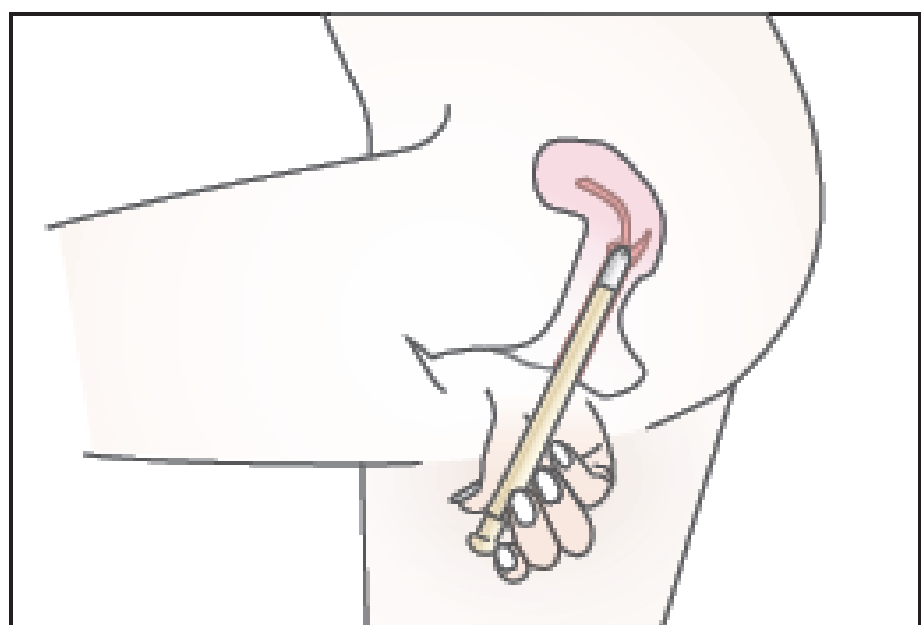
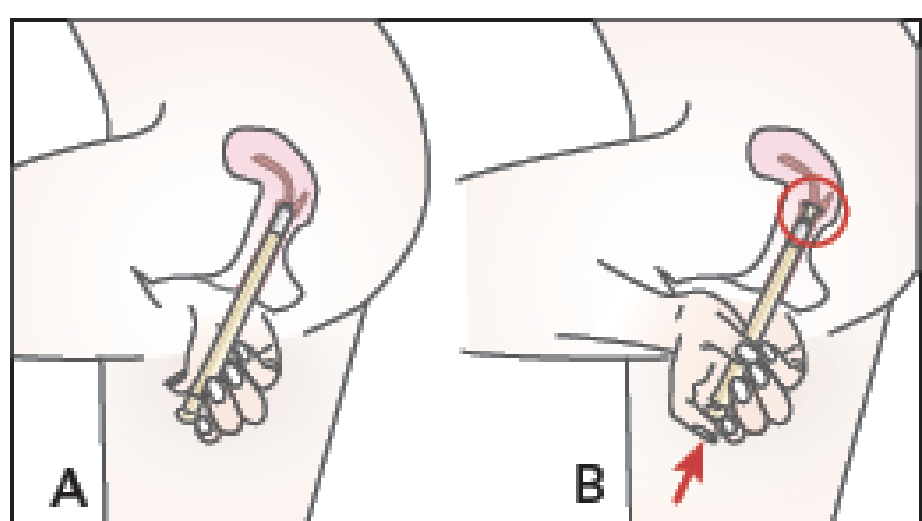
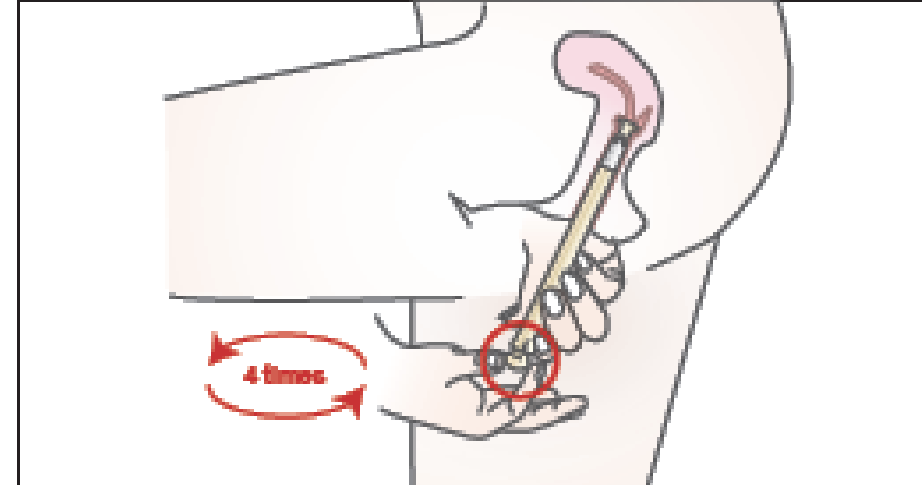
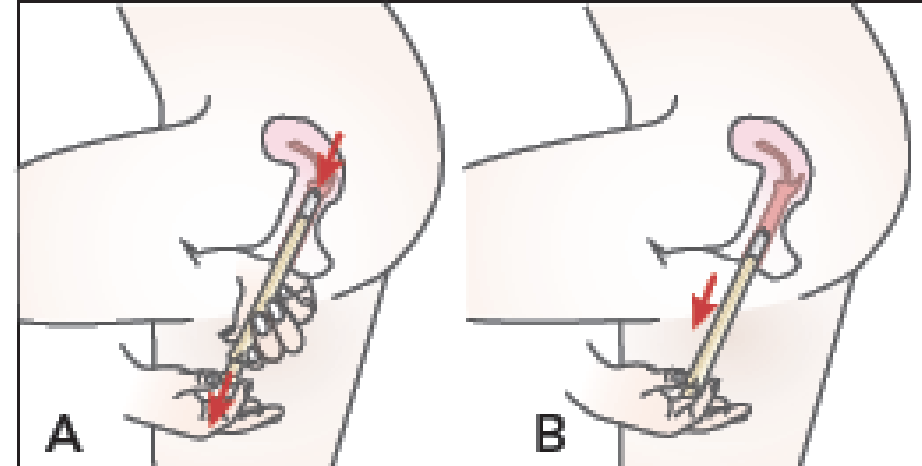
INSTRUCTIONS FOR USE

Preparation

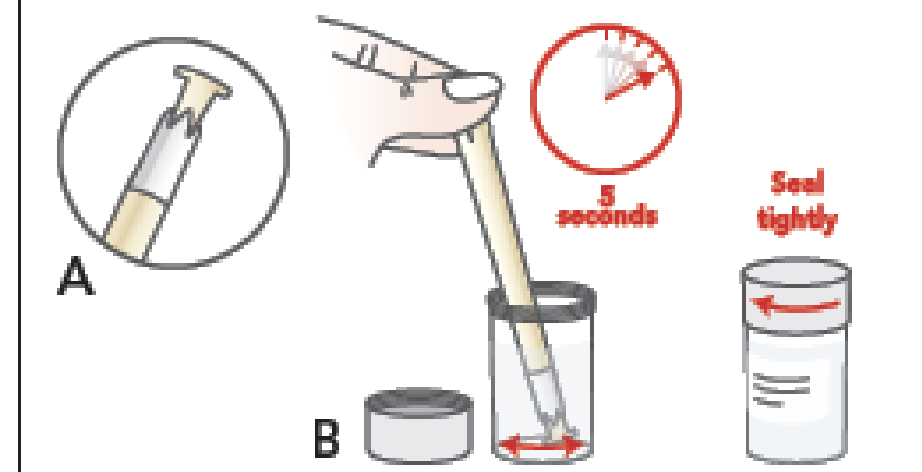
- 1 Wash or sanitize your hands. 
- 2 Open the kit and take out the contents:
 - iPap collector (in plastic bag)
 - Vial (containing liquid)
 - User instructions
 - Return envelope (addressed)
 Unscrew the cap of the vial and place the vial and cap nearby on a stable surface. Take care not to spill the fluid out of the vial. 

Collect the Specimen

- 3 Position yourself standing up with one leg elevated. 

- 4 Take the iPap collector out of the plastic bag. 
- 5 Similar to placement of a tampon, gently push iPap into the vagina tilting it backward until you feel the tip contact your cervix. 
- 6 (A) Hold the collector firmly in place at the finger-grip with one hand. (B) Use the other hand to push the plunger all the way until it stops. As the plunger advances, the shaft will move slightly out of the vagina. The sponge tip of the iPap should now be in contact with the cervix. 
- 7 Still holding the collector firmly in place, twist the knob back and forth 4 times. 
- 8 (A) While holding the collector in place, use your other hand to pull the sponge tip back into the collector. (B) Pull the collector out of the vagina. **NOTE: It is very important that the sponge tip is not exposed when the iPap is being removed from the vagina.** 

Package the Specimen

- 9 (A) Push the plunger forward to expose the tip. (B) Swish the tip in the vial for about 5 seconds. Screw the cap tightly onto the vial. 

Patient	Cell Count	Adequacy	Diagnosis
1	>5000	Satisfactory	WNL
2	>5000	Satisfactory	WNL
3	~2512	Unsatisfactory	
4	>5000	Satisfactory-Conditional	WNL
5	>5000	Satisfactory-Conditional	WNL
6	>5000	Satisfactory	WNL
7	>5000	Satisfactory	WNL
8	>5000	Satisfactory	WNL
9	>5000	Satisfactory-borderline*	WNL
10	>5000	Satisfactory-Conditional	WNL
11	>5000	Satisfactory-Conditional	WNL
12	>5000	Satisfactory-Conditional	WNL
14	~3040	Unsatisfactory	
15	>5000	Satisfactory	WNL, Candida
16	>5000	Satisfactory	WNL, severe bacterial overgrowth
18	>5000	Satisfactory	WNL
19	>5000	Satisfactory	WNL
21	>5000	Satisfactory-Conditional	WNL
22	>5000	Satisfactory	WNL
25	>5000	Satisfactory	WNL
26	>5000	Satisfactory-Conditional	WNL
27	>5000	Satisfactory	WNL

Adequacy

- **Unsatisfactory:** <5,000 squamous cells
- **Satisfactory:** >5,000 squamous cells with representation of transformation zone (metaplastic or glandular cells)
- **Satisfactory-Conditional:** Numerous squamous cells but lacking endocervical and/or metaplastic squamous cells. Unsatisfactory if patient is not postmenopausal
- **Satisfactory-Borderline:** low squamous cells and numerous neutrophils

Diagnosis

- **WNL:** within normal limits

Results: Pathology results showed that 20 out of the 22 samples (91%) had adequate cell counts (5000 cells are required for adequate analysis). Twelve of the samples (54%) had squamous metaplastic or glandular cells indicating sampling from the transformation zone. Seven of the samples (32%) were conditional where the samples are unsatisfactory if patients were not postmenopausal, and one of the samples was borderline with low squamous cells. Study participants gave favorable responses (4 or higher on a 5 point scale) over 88% of the time to questions about the collector instruction's clarity and the devices ease of use..

Conclusions: Initial iPap results show that in most cases this specimen self collection device is able to collect sufficient cellular samples for cervical cytology, including cells from the transformation zone. Additional studies are in progress to expand and confirm these initial findings. Successful introduction of self sampling as part of a cervical cancer prevention program will decrease some of the barriers to screening and therefore improve access. In so doing, this will significantly impact women's health around the world.

	iPap Pilot Study Questionnaire																					
	SAMPLE ID																					
	1	2	3	4	5	6	7	8	9	10	11	15	16	18	19	21	25	12	22			
Previous Pap Test	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y			
Previous HPV Test	N	Y	N	Y	Y	N	Y	Y	N	Y	Y	N	Y	N	Y	N	N	N	N			
Was the "Instructions for Use" (IFU) document clear and easy to understand?	5	4	5	5	3	5	5	5	4	4	5	5	4	4	4	3	4	1				
Was the preparation section (Steps 1-2) of the "Instructions for Use" document clear and easy to understand?	5	4	5	5	3	5	5	5	4	5	4	5	5	5	4	4	5	4	1			
Was the sample collection section (Steps 3-8) of the "Instructions for Use" document clear and easy to understand?	5	4	5	3	4	5	5	5	4	3	4	5	5	5	4	4	4	4	2			
Was the sample packaging section (Steps 9-10) of the "Instructions for Use" document clear and easy to understand?	5	4	5	3	4	5	5	5	4	4	4	5	5	2	4	4	4	4	2			
How easy was it to handle the packaging, i.e., open, close, etc.?	5	5	5	5	5	5	5	5	4	4	5	5	5	5	4	3	5	4	2			
Did the shape and length of iPap make insertion of the collector easy?	4	5	5	5	5	5	5	5	5	4	5	5	5	5	5	3	5	4	2			
What was the level of discomfort (if any) you felt when collecting the sample?	5	5	5	5	5	4	5	3	5	4	5	5	5	5	5	3	3	4	2			
How certain are you that the iPap device was in contact with the cervix during sample collection?	4	5	5	3	3	3	4	4	4	3	2	5	5	5	3	2	4	3	3			
Was it easy to rotate the knob at the end of the plunger in both directions to collect the sample?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	N			
While holding the collector in place with one hand, was the plunger easy to manipulate throughout the collection process with the other hand?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N			
Would you use this self collection process again if it were made available to you?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N			
In the future, would you prefer to use a self-collector rather than visiting a gynecologist for a Pap smear (Cervical sample collection only)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N			

1: Unclear → 5: Very Clear