

Certificate of Analysis

No.: CPBG-20250729-001

Product Name		Prenatal chromosomes probe detection kit (FP-314)		
Lot		250701	Size	10 Tests/box
Quantity		62 boxes	Material No:	7-0652
Valid Until		2026.07.28	Inspection Record No:	CPJY-20250729-001
Quality Standard		Quality standard for finished products of Prenatal chromosomes probe detection kit		
No.	Standard Item	Standard Requirements	Tests Results	Conclusion
1	Exterior	Kit exterior should be intact, without damage, completely marked and clear.	Kit exterior packaging complete, without damage, complete mark and clear	Conform
		The reagent tubes shall be marked clearly and without leakage.	Clear marked tube reagent, with no leakage.	
		The solution in the tubes should be clear without precipitation.	The solution in the tube is clear without precipitation.	
2	Intensity	After effective hybridization with karyotype reference material, the probe should send out fluorescence signal which can be recognized by naked eyes under fluorescence microscope.	Under the fluorescence microscope, the fluorescence signals can be recognized by the naked eye	Conform
3	Probe quality	Sensitivity 1. Sensitivity of CEP18 cyan probe: 100 chromosomes 18 of 50 metaphase cells were analyzed, and at least 98 chromosomes 18 showed 1 cyan fluorescence signal. Sensitivity of CEPX green probe: 100 chromosomes X of 50 metaphase cells were analyzed, and at least 98 chromosomes X showed 1 green fluorescence signal. Sensitivity of CEPY orange probe: 100 chromosomes Y of 50 metaphase cells were analyzed, and at least 98 chromosomes Y showed 1 orange fluorescence signal. 2. Sensitivity of 13q14.2 green probe: 100 chromosomes 13 of 50 metaphase cells were analyzed, and at least 98 chromosomes 13 showed 1 green fluorescence signal. Sensitivity of 21q22.13 orange probe: 100 chromosomes 21 of 50 metaphase cells were analyzed, and at least 98 chromosomes 21 showed 1 orange fluorescence signal.	CEP18 cyan probes: <u>100</u> CEPY orange probes: <u>100</u> CEPX green probes: <u>100</u> 21q22.13 orange probes: <u>100</u> 13q14.2 green probes: <u>100</u>	Conform
		Specificity 1. Specificity of CEP18 orange red probe : 100 chromosomes 18 of 50 metaphase cells were analyzed, and at least 98 chromosomes 18 showed 1 cyan fluorescence signal in the target region. Specificity of CEPX green probe : 100 chromosomes X of 50 metaphase cells were analyzed, and at least 98 chromosomes X showed 1 green fluorescence signal in the target region. Specificity of CEPY orange probe: 100 chromosomes Y of 50 metaphase cells were analyzed, and at least 98 chromosomes Y showed 1 orange fluorescence signal in the target region. 2. Specificity of 13q14.2 green probe : 100 chromosomes X of 50 metaphase cells were analyzed, and at least 98 chromosomes 13 showed 1 green fluorescence signal in the target region. Specificity of 21q22.13 orange probe: 100 chromosomes Y of 50 metaphase cells were analyzed, and at least 98 chromosomes 21 showed 1 orange fluorescence signal in the target region.	CEP18 cyan probes: <u>100</u> CEPY orange probes: <u>100</u> CEPX green probes: <u>100</u> 21q22.13 orange probes: <u>100</u> 13q14.2 green probes: <u>100</u>	
conclusion		According to the standard operation procedure of fluorescence in situ hybridization, the product meets the quality standard of non medical device , it is qualified		
Inspected by:		Zhouting	Reviewed & Approved by:	Fu JINLING
Date:		2025-07-29	Date:	2025-07-29

Certificate of Analysis

No.: CPBG-20250714-001

Product Name		In Situ Hybridization Staining Solution (CL-012)			
Lot		250701		Size	
				5 Tests/tube	10 Tests/tube
				20 Tests/tube	50Tests/tube
Quantity		100Tubes(5Tests/tube) 5252Tubes(10Tests/tube) 3000Tubes(20Tests/tube) 400Tubes(50Tests/tube)		Material No:	
				7-0761	7-0762
				7-0763 7-0764	
Valid Until		2026.07.08		Inspection Record No:	
				CPJY-20250714-001	
Quality Standard		Quality standard for finished products of In Situ Hybridization Staining Solution			
No.	Standard Item	Standard Requirements		Tests Results	
1	Exterior	1.Kit exterior should be intact, without damage, completely marked and clear. 2.The reagent tubes shall be smooth without burr, and the bottle cap shall be tight, no defect or crack. 3.The solution in the tubes should be viscous liquid.		1.Kit exterior should be intact, without damage, completely marked and clear. 2.The reagent tubes shall be smooth without burr, and the bottle cap shall be tight, no defect or crack. 3.The solution in the tubes should be viscous liquid.	
2	Dyeing effect	3 cell droplet samples were re-stained with this reagent, under the fluorescence microscope, the nucleus of the cells showed blue fluorescence.		3 cell droplet samples were re-stained with this reagent, under the fluorescence microscope, the nucleus of the cells showed blue fluorescence.	
conclusion		According to In Situ Hybridization Staining Solution finished product inspection standard operating procedures, the product meets the quality standard of In Situ Hybridization Staining Solution, it is qualified			
Inspected by:		Zhouwei		Reviewed & Approved by:	
Date:		2025-07-14		Fu JINLING	
				Date:	
				2025-07-14	

