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	sensibility	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:100 CEPY orange probes:100 CEPX green probes：100 21q22.13orange probes:100 13q14.2 green probes：100	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:100 CEPY orange probes:100 CEPX green probes：100 21q22.13orange probes:100 13q14.2 green probes：100	

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

Digitally signed by Rusu Ghenadie
Date: 2025.10.24 10:08:16 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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	Conclusion
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.	**Conform**
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.	**Conform**

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:**	**Fu JINLING**
Date:	2025-07-14	**Date:**	2025-07-14