

★ For Newborn Screening Agencies

I. Organizational Management																
(I) Institutional settings and management requirements			(II) Personnel requirements				(III) Laboratory construction requirements			(IV) Rules construction				(V) Information system construction		
1. Does the institutional settings meet the requirements?	2. Does the management of the cooperating blood collection agencies meet the requirements?	3. Is there a specialist clinic for NBS?	4. Whether the qualification of the director of the NBS centre meets the requirements?	5. Whether the laboratory technicians meet the requirements /qualifications?	6. Whether the diagnosis and treatment clinicians meet the requirements /qualifications?	7. Do personnel engaged in NBS receive continuing education?	8. Does the laboratory instruction meet the requirements?	9. Whether the equipment configuration meets the requirements?	10. Are there perfect and constantly updated personnel rules?	11. Are there perfect and constantly updated rules for the diagnosis and treatment of IEMs?	12. Are there perfect and constantly updated rules for case management?	13. Are there perfect and constantly updated rules for archives management?	14. Are there perfect and constantly updated rules for laboratory equipments and specimens management?	15. Is there a well-established information system for screening data management?	16. Is there a well-established information system for case records, diagnosis and treatment, and follow-up management?	
II. Screening Management																
(VI) Pre-screening	(VII) Pre-testing quality control				(VIII) Testing quality control				(IX) Post-testing quality control				(X) Follow up	(XI) Testing data and specimen storage		
17. Whether the informed consent meets the requirements?	18. Whether the consumables for blood collection meet the requirements?	20. Completeness of specimen information.	22. Recollection rate of unqualified specimens.	24. Intime-delivery rate of specimens .	25. Completeness of the laboratory testing SOP.	27. Is internal quality control for testing performed regularly?	29. Is the CV of Phe testing meet the requirements?	31. Status of the participation of external quality assessment (EQA).	33. EQA passing status of the TSH testing.	34. Rate of timely-issued testing reports.	36. Are there quality control measures when issuing reports?	38. Notification rate of children with positive CH testing results.	40. Recall rate of children with positive CH testing results.	42. Positive predictive value of CH screening testing.	43. False negative rate of CH screening testing.	46. Whether the storage of testing data meets the requirements?
	19. Whether the equipment and reagents meet the requirements?	21. Unqualified specimen rate.	23. Specimen turnaround time before testing.	26. Is the performance of laboratory measurement systems checked regularly?	28. Is the internal quality control for PKU and TSH laboratory testings meet the requirements?	30. Is the CV of TSH testing meet the requirements?	32. EQA passing status of the Phe testing.	35. The standardization of testing reports.	37. Notification rate of children with positive PKU testing results.	39. Recall rate of children with positive PKU testing results.	41. Positive predictive value of PKU screening testing.	43. False negative rate of PKU screening testing.	45. Positive (or negative) follow-up rate	47. Whether the specimen storage meets the requirements?		
III. Diagnosis and treatment management																
(XII) Case diagnosis				(XIII) Treatment and follow-up				(XIV) Treatment effect				(XV) Medical record management				
48. The standardization of medical records.	49. Rate of standard diagnosis of PKU .	51. Rate of standard diagnosis of CH.	52. Proportion of CH cases diagnosed at the newborn stage.	53. Proportion of standard treatment for PKU cases.	54. Proportion of PKU cases starting treatment from the neonatal period.	56. Proportion of PKU cases regularly evaluated physical development status.	58. Proportion of standard treatment for CH cases.	60. Proportion of CH cases regularly monitored FT4/TSH levels.	62. Proportion of CH cases regularly evaluated mental development status.	64. Proportion of PKU cases with normal mental development status.	66. Proportion of CH cases with normal mental development status.	68. Are there archives established for each CH case?				
	50. Proportion of PKU cases diagnosed at the newborn stage.				55. Proportion of PKU cases regularly monitored Phe levels.	57. Proportion of PKU cases regularly evaluated mental development status.	59. Proportion of CH cases starting treatment from the neonatal period.	61. Proportion of CH cases regularly evaluated physical development status.	63. Proportion of PKU cases with normal physical development status.	65. Proportion of CH cases with normal physical development status.	67. Are there archives established for each PKU case?					

★ For Blood Collection Agencies

I. Organizational Management					II. Process Management									III. Outcome management		
(I) Personnel requirements		(II) Institution construction requirements			(III) Publicity and health education		(IV) Blood collection							(V) Informed notification	(VI) Quality of specimen	(VII) Archives preservation
1. Whether the blood collectors meet the requirements/qualifications?	2. Whether the blood collectors have received relevant training?	3. Biosafety	4. Whether regularly participate the quality control of the NBS centers?	5. Whether the information management meets the specifications?	6. Is there any NBS publicity and health education?	7. Whether the informed consent meets the requirements?	8. Whether the blood collection and DBS making meet the requirements?	9. Is the blood collection registration card regulated filled?	10. Whether the specimen storage meets the requirements?	11. Whether the specimen delivery meets the requirements?	12. Whether the specimen handover meets the requirements?	13. Whether the specimen recollection records meets the requirements?	14. Proportion of signed informed consent.	15. Unqualified specimen rate.	16. Whether the preservation of archives meets the requirements?	