To be completed by treating clinician and returned to CDC within 14 days of DAT administration

Appendix 4: Diphtheria Antitoxin (DAT) Treatment and Adverse Effects Form

Patient ID	Name
Drug Diphtheria Antitoxin	Date of Request ☐☐ ☐☐ ☐☐ Month Day Year

Diphtheria Antitoxin is currently not licensed in the United States. The National Center for Immunization and Respiratory Diseases of the Centers for Disease Control and Prevention (CDC) is the national center for consultation of suspected diphtheria cases and is responsible for providing diphtheria antitoxin for therapy. CDC has received approval to distribute this product to physicians as an Investigational New Drug (IND) in accordance with requirements of the Food and Drug Administration (FDA). Under the provisions of our IND protocol we must obtain clinical information on each patient who has received DAT.

For each patient who develops any serious adverse events (SAE) after DAT administration including those listed in the IND under **Section 7.2 Definitions of Adverse Events**, please contact the CDC diphtheria duty officer or CDC Emergency Operations Center at (770) 488-7100 within 24 hours of occurrence or as soon as possible (see Section 7.3 Treating Clinician Reporting Requirements to CDC).

For any patient receiving DAT, including patients who develop non-serious adverse events (AE) after receiving DAT, please complete and return this form within 14 days of DAT administration or as soon as possible to CDC's Meningitis and Vaccine Preventable Diseases Branch via email at wvh5@cdc.gov or via FAX to (678) 669-2771.

SENSITIVITY TESTING

Was Sensitivity Testing Done Prior to Antitoxin Administration? ☐ Y = Yes N = No	If Yes, at What Site? ☐ Skin ☐ Eye ☐ Other Other
What Dosage And Diluent?	Result

ANTITOXIN ADMIN

Antitoxin Given by Intravenous (IV)

Dates DAT Given MM DD YYYY	Time DAT Given HH:MM	Vials Given	Lot Number

ANTITOXIN REACTIONS

(Excluding Reactions During Sensitivity Testing)

Reaction	Y = Yes N = No	If Yes, How Long After DAT Given?	Duration of Reaction
General: Fever	☐		
Chills	☐		
Urticaria	☐		
Swelling/Edema	☐		
Anaphylaxis	☐		
Serum Sickness	☐		
Rash: Macular/Papular	☐		
Vesicular	☐		
Other	☐		
Other Hypersensitivity	☐		
Other Reaction	☐		

Give Details For All Adverse Effects, Including Location of Urticaria, Rash, Swelling, or Other Localized Adverse Effects.

Was Any Treatment Given For an Adverse Effect? If Yes, Describe.

☐ Y = Yes N = No

Was Antitoxin Administration Stopped Due to an Adverse Effect? If Yes, Describe.

☐ Y = Yes N = No

This document can be found on the CDC website at:
https://www.cdc.gov/diphtheria/downloads/appendix-2-adverse-event-report.pdf